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No. 08-624

IN THE
Supreme Court of the United States

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S,
Petitioners,

v.

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a form of declaratory judgment called a "civil action to obtain patent certainty," 21 U.S.C. § 355(j)(5)(C), premised on an underlying cause of action for patent infringement, remains justiciable under Article III of the Constitution after the pioneering drug company defendant holding the patent irrevocably covenants not to sue the generic drug company plaintiff for infringement of the patent at issue.

2. Whether the causation necessary to support constitutional standing exists where the claimed injury in fact traces to a patent holder's compliance with a mandatory patent listing obligation imposed by a federal statute and backed by criminal sanction.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, petitioners hereby state that:

(1) Forest Laboratories, Inc. does not have a parent corporation, and no publicly held corporation owns 10% or more of Forest Laboratories, Inc.'s stock.

(2) Forest Laboratories Holdings, Ltd. is a wholly owned subsidiary of Forest Laboratories, Inc. Forest Laboratories, Inc. is the only publicly held corporation that owns 10% or more of Forest Laboratories Holdings, Ltd.'s stock.

(3) H. Lundbeck A/S does not have a parent corporation and no publicly held corporation owns 10% or more of H. Lundbeck A/S's stock.

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INTRODUCTION

In a case of extreme significance to the entire pharmaceutical industry, a divided panel of the Federal Circuit has interpreted the Hatch-Waxman Act[1] in a manner that upsets the careful balance Congress established in that landmark statute as between providing incentives for pioneering companies—such as Petitioner Forest (collectively Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S)—and encouraging the entry of generic enterprises—such as Respondent Caraco Pharmaceutical. In doing so, the panel has upset settled law and tugged at foundational principles of judicial power under Article III of the Constitution. Sweepingly interpreting this Court's decision two Terms ago in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007), the divided panel—over a sharp dissent by Judge Daniel Friedman—did great violence to the congressionally ordained structure erected almost a generation ago by Hatch-Waxman. This will usher in an era of destabilizing and counterproductive patent litigation. Review is warranted now.

The Hatch-Waxman Act stands at the interface of the patent statutes and the approval process for pioneer and generic drugs under the food and drug laws. Notwithstanding its profound importance to the whole of the pharmaceutical industry, Hatch-

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[1] This is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

Waxman has been considered by this Court only twice in the statute's 24-year lifespan.[2] Even with those two decisions, however, never before has this Court addressed a question arising under the core provisions of the Hatch-Waxman Act, let alone such a case presenting grave concerns under Article III of the Constitution.

Contrary to a large body of law holding that covenants not to sue moot suits premised on the relevant cause of action to which the covenant relates, a divided Federal Circuit panel held in this case that a new type of declaratory judgment suit created by Hatch-Waxman changed the previously clear Article III consequences of such covenants. To our knowledge, never before has a court stripped a class of litigants of their pre-existing right to avoid suit by granting an enforceable covenant not to sue—thereby functionally conscripting them as unwilling litigants—especially in the absence of a clear directive from Congress to do so.

The Federal Circuit thought its result was supported by this Court's decision two terms ago in *MedImmune*. But *MedImmune* did not involve Hatch-Waxman or its newly devised declaratory judgment suits designed to probe the boundaries of Article III. *See* 35 U.S.C. § 271(e)(5) (authorizing unique form of declaratory judgment action "to the

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[2] *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005) (holding preclinical studies fell within the Section 271(e)(1) exception to patent infringement for uses reasonably related to developing and submitting information to the FDA for purposes of that agency's regulation of drugs); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (considering whether this drug-based exception also applied to medical devices).

extent consistent with the Constitution"). To the contrary, *MedImmune* held only that a patent licensee could pay royalties under protest without mooting its right to bring a declaratory judgment action to determine whether the licensed patent was valid and not infringed. Nothing in that decision speaks to whether Hatch-Waxman declaratory judgment actions remain justiciable means to resolve a dispute about infringement after the patent holder grants a covenant not to sue.

For decades, the lower courts and the Food and Drug Administration ("FDA") have been grappling with the complexities Hatch-Waxman creates for patent litigation. That this Court's intervention is needed to clarify the operation of Hatch-Waxman—and the application of Article III to its regime—is loudly testified to by the invalidation of numerous Hatch-Waxman FDA regulations and interpretations leading up to the adoption of Hatch-Waxman Act-specific declaratory judgment suits.[3]

In one of the cases invalidating an FDA regulation, the D.C. Circuit suggested that declaratory judgment suits might smooth the rough edges of Hatch-Waxman. Surveying the potential pitfalls of such a purported solution, however, the court recognized:

> [Generic drug company] Mylan has also noted what may be a more serious fly in the

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[3] *See, e.g., Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (invalidating FDA's "successful defense" Hatch-Waxman regulation); *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 42, 47 (D.D.C. 2000) (invalidating a different FDA Hatch-Waxman regulation construing the statutory phrase "a decision of a court").

> (patented) ointment. In order to satisfy the Constitution's case or controversy requirement, a party filing a declaratory judgment action must show that there is a controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

Mova, 140 F.3d at 1073 (internal quotation marks omitted).

Notwithstanding such a cautionary note, Congress decided to adopt precisely such a declaratory judgment solution in 2003 to the problems emergent in the Hatch-Waxman regime. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1335 (Fed. Cir. 2007) (discussing Congress's creation of the so-called "civil action to obtain patent certainty").

The *Mova* court actually saw two related "flies in the ointment" for expanded use of declaratory judgments under Hatch-Waxman: (1) the Federal Circuit's "reasonable apprehension of suit" limitation on when declaratory relief is viable in patent suits; and (2) the Article III requirement of a "Case or Controversy." *MedImmune* eliminated the former as an obstacle. 127 S. Ct. at 774 n.11. But *MedImmune* did not address, much less resolve, the entirely distinct question of the limits of Hatch-Waxman declaratory judgment actions as cabined by Article III.

Accordingly, there is an urgent need for this Court to authoritatively construe the Hatch-Waxman form of declaratory judgment action and resolve the constitutional question *MedImmune* did not resolve. This case should be chosen as the

vehicle because of its exceptional importance to the business community. At the *en banc* stage, representatives of all of the major interests regulated or touched by Hatch-Waxman asked the Federal Circuit to reconsider its erroneous decision: pioneer drug companies, a leading generic drug company, as well as pharmaceutical and biotechnical trade associations. Urging rehearing, this broad coalition of shared interests argued vigorously that the divided panel's decision radically rebalanced congressionally designed incentives to innovation and for the introduction of generic competition, while expanding the uses of Hatch-Waxman declaratory judgment suits beyond the bounds of the Constitution and of congressional intent. Indeed, one of Caraco's generic competitors was alarmed that the Federal Circuit's decision robs generic companies of the benefits Congress intended to confer on the first generic companies to challenge pioneer patents. Left unchecked, the decision will trigger a new wave of litigation the drafters of Hatch-Waxman did not remotely intend.

OPINIONS BELOW

The Federal Circuit's decision is reported at 527 F.3d 1278 (Fed. Cir. 2008) and reprinted in the Appendix ("App.") at 1a. The order of the United States District Court for the Eastern District of Michigan dismissing for lack of subject matter jurisdiction is reprinted at App. 47a.

JURISDICTION

The court of appeals rendered its decision on

April 1, 2008, and denied a timely petition for rehearing and rehearing en banc on June 24, 2008.[4] App. 45a. On September 12, 2008, Chief Justice Roberts extended the time for filing this petition to and including November 6, 2008. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

Article III, Section 2, Clause 1 of the Constitution provides in relevant part that "[t]he judicial Power shall extend to all Cases, in Law and Equity [and] Controversies . . . ." Pursuant to Court Rule 14.1(f), pertinent statutory provisions are reprinted in the Appendix at 106a-110a.

STATEMENT OF THE CASE

A. STATUTORY BACKGROUND

1. The Hatch-Waxman Act governs the approval of all drugs introduced into interstate commerce. 21 U.S.C. § 355(a). Under the Act, a pioneer drug company must obtain approval from the FDA for a new drug by submitting a New Drug Application ("NDA"). Pioneer applicants are required to file with the FDA the patent number and expiration date of all patents that claim the drug or claim a method of using the drug, if a claim of patent infringement could reasonably be asserted were the drug to be manufactured, used, or sold by another. 21 U.S.C. § 355(b)(1). The FDA is then assigned a ministerial duty to list these patents in a publication commonly

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[4] The court of appeals granted a 14-day extension of time in which to file a petition for rehearing and rehearing en banc.

known as the "Orange Book." Drugs approved by the FDA are referred to as "listed drugs." 21 U.S.C. § 355(j)(2)(A)(i). The patents listed in the Orange Book for each listed drug are referred to as "listed patents." *See* 21 C.F.R. § 314.53(f).

Failure to submit the patent information is a ground for denying NDA approval. 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.150(a)(2)(v) (1999); 21 C.F.R. § 314.53(b),(c) (2004). Indeed, failure to provide an accurate and complete submission of patent information subjects the holder to potential criminal liability. 21 C.F.R. § 314.53(c)(2)(i)(Q) (2004).

2. The Hatch-Waxman Act streamlines approval for generic versions of listed drugs by allowing generic drug manufacturers to submit an "Abbreviated New Drug Application" ("ANDA"). 21 U.S.C. § 355(j). If an ANDA applicant desires approval to market a generic version of the listed drug prior to expiration of a patent covering the listed drug, the ANDA applicant must include a certification that the patent covering the listed drug is invalid or not infringed by the drug that is the subject of the ANDA. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). This is known as a "Paragraph IV" certification. Submission of a Paragraph IV certification constitutes an "artificial" act of infringement. 35 U.S.C. § 271(e)(2); *Eli Lilly*, 496 U.S. at 676.

The first applicant to submit an ANDA for a listed drug that includes a Paragraph IV certification against a listed patent is eligible to receive 180 days of exclusive generic marketing. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). "We will call this Edenic moment of freedom from the pressures of the

marketplace the statute's 'exclusivity period.'" *Mova*, 140 F.3d at 1064-65. The FDA may not approve any subsequent ANDA until after this 180-day exclusivity period has expired. The purpose of the exclusivity period is to incentivize generic drug companies to take on the economic and litigation risks inherent in challenging pioneer patents. *Id.* at 1075. The exclusivity period begins to run (1) when the first Paragraph IV ANDA filer commercially markets its drug (the commercial marketing trigger), or (2) on the date of a court decision holding the patent that was the subject of the certification to be invalid or not infringed (the court-judgment trigger). 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

3. In 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernizaton Act of 2003 ("Medicare Modernization Act"). *See supra* n.1. The Medicare Modernization Act amended the Hatch-Waxman Act by adding a new provision for a "civil action to obtain patent certainty" (hereafter "CAPC"). 21 U.S.C. § 355(j)(5)(C). Under this provision, if the holder of the NDA for a listed drug does not bring an infringement action within 45 days of receiving notice of a Paragraph IV certification for that drug, the ANDA applicant may bring a civil action for a declaratory judgment that the patents at issue are invalid or not infringed. 21 U.S.C. § 355(j)(5)(C)(i).[5]

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[5] The Medicare Modernization Act also revised the framework under which the first Paragraph IV filer can forfeit its exclusivity period if it does not market a drug within specified periods of time. 117 Stat. at 2457-60, Section 1102. These forfeiture provisions, however, do not apply to ANDAs (such as the ANDA relevant to this case) containing Paragraph IV

The Medicare Modernization Act provides that federal courts have subject matter jurisdiction over such declaratory judgment actions "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). The purpose of this expression of intent was to test the boundaries of this new form of declaratory judgment against Article III. *See* App. 10a-11a (relying on statement of Senator Kennedy).

B. Factual Background

1. Forest markets the blockbuster drug Lexapro® ("Lexapro"), which is used to treat depression and generalized anxiety disorder. As part of the mandatory process for avoiding penalties and obtaining FDA approval for Lexapro, Forest filed the necessary information concerning two patents with the FDA: U.S. Patent No. Re. 34,712 (the '712 patent) and U.S. Patent No. 6,916,941 (the '941 patent).

Ivax Pharmaceuticals, Inc. ("Ivax") was the first ANDA applicant to file a Paragraph IV certification for the '712 and '941 patents. App. 12a. Ivax is therefore eligible for up to 180 days of generic market exclusivity for each patent, which will begin to run on the earlier of (1) the day Ivax begins marketing its generic drug or (2) the day a court determines that, for each such patent at issue, the patent is invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

In response to Ivax's Paragraph IV certification,

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certifications that were filed before December 8, 2003. 117 Stat. at 2460, Section 1102(b).

which represents an act of infringement under 35 U.S.C. § 271(e)(2), Forest sued Ivax for infringement of the '712 patent. Ivax counterclaimed that the '712 patent was invalid and unenforceable. Forest prevailed completely in that litigation, obtaining a judgment that the '712 patent was valid and enforceable, along with a stipulation that Ivax's ANDA infringed that patent. App. 12a-13a. This judgment was affirmed in its entirety on appeal. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007).

2. In May 2006, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed ANDA 78-219 for Lexapro with the FDA. This ANDA included a Paragraph IV certification for the '712 and '941 patents. App. 15a-16a. Caraco's was the third Paragraph IV certification on the '712 patent and the seventh Paragraph IV certification on the '941 patent. In response to ANDA 78-219, Forest sued Caraco for infringement of the '712 patent (but not the '941 patent). App. 16a. That litigation is ongoing.

When Forest did not sue Caraco for infringement of the '941 patent, Caraco filed a separate action seeking a declaration that its ANDA did not infringe the '941 patent. App. 16a, 83a. Caraco did not contest the validity of the '941 patent. *Id.*

Forest then moved to dismiss Caraco's declaratory judgment action for lack of jurisdiction. App. 17a. Forest later granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent to confirm that no case or controversy existed between Forest and Caraco. The covenant provided as follows:

> [Forest] hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use sale, or offer for sale or importation of the generic products described by ANDA 78-219.

App. 19a-20a; 103a-104a.

C. PROCEEDINGS BELOW

On May 31, 2007, the district court granted Forest's motion to dismiss. App. 47a. Ruling from the bench, the court explained that because Forest had granted Caraco a covenant not to sue, Caraco suffered *no risk* of being sued for infringement and its complaint was "asking for the same relief as they already have." Hence, a controversy no longer existed under Article III, App. 77a-78a, and Caraco could not be found liable for infringement.

A divided panel of the Federal Circuit reversed. The majority held that, despite the covenant not to sue, "Caraco's declaratory judgment action presents a continuing Article III controversy" because, "in the context of the Hatch-Waxman framework, Forest's covenant not to sue did not eliminate the controversy between the parties." App. 2a.

Addressing the three constitutional requirements for standing, *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998), the Federal Circuit *first* concluded that there was an injury-in-fact because Caraco was being excluded from the drug market by the '941 patent. App. 24a-25a. Specifically, because Ivax was the first ANDA-filer

with respect to Lexapro, Caraco could not enter the market for generic Lexapro until Ivax's 180-day exclusivity period had expired. App. 26a-27a. A subsequent Paragraph IV ANDA filer such as Caraco can trigger Ivax's exclusivity period only by obtaining a judgment that the '941 patent is either invalid or not infringed. App. 27a-28a.

Second, the Federal Circuit concluded that Caraco's injury is traceable to Forest. The court stated that "Forest's listing of the '712 and '941 patents in the Orange Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both patents are invalid or not infringed by its generic drug." App. 27a. The court concluded that Forest's listing, rather than the Hatch-Waxman Act, caused Caraco's injury by preventing Caraco from entering the marketplace. *Id.*

Third, the Federal Circuit concluded that Caraco's injury is redressable by a declaratory judgment that the '941 patent is not infringed. App. 27a-28a. According to the court of appeals, "[i]f Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as swiftly as possible." App. 28a.[6] The Federal Circuit emphasized that its

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[6] The dissenting judge took issue with that claim (see below). In addition, on September 2, 2008, after the decision here issued, a new patent issued for Lexapro—U.S. Patent No. 7,420,069 ("'069 patent"). The issuance of this new patent underscores both that Caraco is *not* close to market entry, and

reading of the purposes of the CAPC declaratory action created by Congress in 2003 was consistent with the "remarks of Senator Kennedy." App. 30a.

Addressing the other two justiciability doctrines, the Federal Circuit concluded that Caraco's declaratory judgment claim was ripe and not moot. App. 31a-36a. Although the court below conceded that Forest's covenant "would moot Caraco's case" if a threat of an infringement lawsuit "was the *only action* allegedly taken by Forest that effectively excluded Caraco from the marketplace," App. 34a (emphasis added), the panel nevertheless concluded that the covenant did not moot this case because "Caraco is alleging that it has been denied entry to the market in a manner that is unique to the Hatch-Waxman context." App. 35a.

Judge Friedman dissented. Although agreeing that Caraco's declaratory judgment claim "stems from and is based upon particular provisions of the Hatch-Waxman Act," not from any danger of damages for infringement, App. 38a, Judge Friedman maintained that Caraco's declaratory judgment claim was unripe because it was based on contingencies that may never come to pass (such as a victory by Caraco in pending patent litigation with Forest over the '712 patent). App. 40a-41a.

Judge Friedman further opined that the

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that the Federal Circuit mistakenly believed that the exclusive source of Caraco's market exclusion is Forest's purportedly discretionary decision to list the '941 patent in the Orange Book. Notably, Caraco has also failed to file a Paragraph IV certification on the '069 patent (listed September 23, 2008), though Forest has already received nine such certifications from other generic companies.

majority's "theory" was inconsistent with Congress's policy judgment to favor the *first* ANDA filer. App. 40a. In the absence of an "indication that [Senator Kennedy's] statements reflected the views of the majority of the committee or of the Senate, or the sponsors of" the Medicare Modernization Act in 2003, the dissenting judge was unwilling to conclude that such statements were an "adequate basis for determining the scope and meaning of this legislation." App. 41a. Judge Friedman also pointed out that the majority was glossing over Senator Kennedy's express caveat: "We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue . . . ." App. 42a.

Overall, in light of Forest's covenant not to sue, Judge Friedman would have held that, "'under all the circumstances,'" there was not a "'substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of declaratory judgment.'" App. 41a. (quoting *MedImmune*, 127 S. Ct. at 771).

Forest sought *en banc* review or panel rehearing. Numerous amicus briefs were filed in support of rehearing.[7] Although it called for a response, the Federal Circuit ultimately denied the petition.

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[7] In addition to support by Ivax, the generic first ANDA filer, Forest had the support of pioneer drug companies Merck & Co., Inc. and Pfizer, Inc., industry trade associations the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization, and the public interest organization, the Washington Legal Foundation.

REASONS FOR GRANTING THE WRIT

The Federal Circuit's exclusive appellate jurisdiction over patent disputes, 28 U.S.C. § 1295(a)(1), (a)(4), precludes the emergence of a split among the Circuits on the questions presented. *Compare* S. Ct. R. 10(a). Nevertheless, the path by which the Federal Circuit reached its conclusion ran roughshod over decisions of this Court, while feeding circuit splits and intra-circuit divisions within the Federal Circuit itself.

Despite conceding that a viable infringement action was terminated by virtue of the covenant not to sue, *see* App. 34a, the Federal Circuit's conceptual framework required it to recast the familiar cause of action for patent infringement as a cause of action Congress has never seen fit to create. App. 35a-36a. Hatch-Waxman's operation is thus seriously distorted. Additionally, this judicial legerdemain ignores the bedrock constitutional requirement that a valid injury in fact sufficient to support standing exists only where such injury results from invasion of a "legally protected interest." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). And a "legally protected interest" here is nothing other than a congressionally created cause of action. Since at least one other Circuit has also recently announced, in derogation of *Lujan*, that the legal protectability requirement confuses standing with the merits, this Court should intervene to clarify that *Lujan* applies equally to complex regulatory regimes like Hatch-Waxman. There is no standing to press claims for redress for an injury based on a nonexistent cause of action.

The Federal Circuit decision also violated this

Court's case law by cavalierly tracing causation to actions by third parties not before the court. Here, the court of appeals held that Forest's decision to list its '941 patent in the Orange Book caused Caraco's injury. But Forest's action was mandatory, not discretionary. It is not Forest's purported listing decision (in reality a listing *obligation*) that prevented Caraco from freely entering the relevant drug market. Instead, it was Congress's decision to exclude Caraco from the market for the purpose of favoring the first ANDA filer (here Ivax) that is the cause of Caraco's claimed injury.

Other Circuits have found that no standing exists when causation for an alleged injury traces to sovereign legal action, rather than to discretionary private action. The Federal Circuit's decision in this case conflicts with those rulings.

This petition should be granted for the further reason that the decision below threatens to subvert Article III and to destabilize the careful balance Congress struck among the rights of pioneer drug companies, ANDA first filers, and subsequent ANDA filers. In its quest to serve the laudable goal of speeding the introduction of generic drugs into the market, the Federal Circuit lost sight of the stopping points in the Hatch-Waxman regime and the law of justiciability. Together, those intertwined requirements serve to protect the substantial investments in innovation pioneer companies incur, as well as the large risks ANDA first filers accept when they attempt to prove a listed patent is either invalid or not infringed.

I. CONTRARY TO SUPREME COURT AND CIRCUIT DECISIONAL LAW, THE FEDERAL CIRCUIT'S DECISION FINDS STANDING WHERE NO "LEGALLY PROTECTED INTEREST" IS AT STAKE.

1. This Court has repeatedly held that not every injury is sufficient to create a constitutional case or controversy. *See, e.g., Raines v. Byrd*, 521 U.S. 811, 825-26 (1997); *Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc.*, 454 U.S. 464, 485-86 (1982). To the contrary, an injury must be actionable in order to give rise to constitutionally cognizable injury. This is a corollary of the point that not every "case" or "controversy" can give rise to Article III jurisdiction. Instead, "the Constitution's central mechanism of separation of powers depends largely upon common understanding of what activities are appropriate to legislatures, to executives, and to courts." *Lujan*, 504 U.S. at 559-60.

Consider *McConnell v. FEC*, 540 U.S. 93 (2003). In that case, certain plaintiffs challenged a particular provision of the Bipartisan Campaign Finance Reform Act that relaxed prior limits on "hard money" contributions. That particular subgroup of plaintiffs argued that this statutory expansion of contribution limits injured them by reducing their ability to participate in elections on an equal footing based merely on their economic status. The majority held that the plaintiffs lacked standing because the ability to compete in an election only so long as all participants have equal resources is not a "legally cognizable right." *Id.* at 227. *See also Warth v. Seldin*, 422 U.S. 490, 500 (1975) (standing "often turns on the nature and

source of the claim asserted.").

The lower courts have largely followed the instruction of this Court to test assertions of injury for standing purposes to determine if they are premised upon a valid cause of action. Take, for instance, the Fourth Circuit's opinion in *Salt Institute v. Leavitt*, 440 F.3d 156 (4th Cir. 2006). *Salt Institute* held that since the Information Quality Act created no private right of action and there was no common law cause of action to correct false information, the absence of any legally cognizable cause of action required the suit to be dismissed for want of standing. *Id.* at 158-59.[8]

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[8] *See also Pichler v. UNITE*, 542 F.3d 380, 390-92 (3d Cir. 2008) (following *Lujan*); *Neese v. Johanns*, 518 F.3d 215, 219 (4th Cir. 2008) (same); *AT&T Mobility, LLC v. National Ass'n for Stock Car Auto Racing, Inc.*, 494 F.3d 1356, 1360-62 (11th Cir. 2007) (same); *Morlan v. Universal Guar. Life Ins. Co.*, 298 F.3d 609, 621 (7th Cir. 2002) (Posner, J.) ("The possession of a legally protectable interest is a prerequisite to suing because otherwise the possessor of that interest would find himself unable to enforce it if another person, an officious intermeddler, had brought suit to enforce it (like a bounty hunter) first."); *Potthoff v. Morin*, 245 F.3d 710, 717-18 (8th Cir. 2001) ("an abstract constitutional right is not justiciable unless a legally protectible interest is at stake"); *Claybrook v. Slater*, 111 F.3d 904, 906-07, 909 (D.C. Cir. 1997) (following *Lujan*); *Alliance Against IFQs v. Brown*, 84 F.3d 343, 351-52 (9th Cir. 1996) (rejecting particular cause of action under the Magnuson Act where the fishermen's claimed injury was based on an interest belonging to the State of Alaska and thus not "an invasion of a legally protected interest . . . of the [plaintiffs]."") (internal quotation omitted); *In re Joint E. & S. Dist. Asbestos Litig.*, 78 F.3d 764, 780 (2d Cir. 1996) (following *Lujan*); *Association for Retarded Citizens of Dallas v. Dallas County Mental Health & Mental Retardation Ctr. Bd. of Trs.*, 19 F.3d 241, 244 (5th Cir. 1994) (same).

Or consider *Day v. Bond*, 500 F.3d 1127 (10th Cir. 2007), which addressed whether a Kansas law granting in-state tuition benefits to illegal aliens was preempted by a federal immigration statute. The Tenth Circuit held there was no standing because the immigration statute did not give rise to a private right of action: "The merits issue is whether [the Kansas statute] is preempted by 8 U.S.C. § 1623. The standing question is whether § 1623 creates a private cause of action. Each of these issues is separate and independent . . . ." *Id.* at 1136-39.

The same is true here. The merits question is whether Caraco's generic Lexapro would infringe Forest's '941 patent. The standing question is whether the civil action to obtain patent certainty ("CAPC") in 21 U.S.C. § 355(j)(5)(C) creates a private right of action apart from redressing disputes over infringement. The two questions are fully distinct, and the Federal Circuit was wrong to conclude that injury divorced from what is exclusively an infringement cause of action can support constitutional standing.[9]

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[9] *Day v. Bond*, which applies the analysis required by this Court's cases should be contrasted with outlier decisions, which reflect confusion about how to act on the principle that standing and merits analysis should be kept separate. *See, e.g., Club Italia Soccer & Sports Org., Inc. v. Charter Twp. of Shelby, Mich.*, 470 F.3d 286 (6th Cir. 2006). In that case, the Sixth Circuit assailed a district court decision that had held "because Plaintiff does not allege a legally protectable interest, Plaintiff does not have standing." *Id.* at 292. According to the Sixth Circuit, "[t]his conclusion improperly grafts the standing inquiry onto the merits of Plaintiff's due process claim." *Id.* Such an analysis harkens back to the outdated view that the existence of a legally protected right is irrelevant to

2. The Federal Circuit's principal error was to devise a cause of action of its own making, premised on a nonexistent right to seek review of any action by a pioneer drug company that contributed to preventing a generic company from marketing its drug as soon as possible. Relying on its earlier decision in *Novartis*, 482 F.3d at 1345, the Federal Circuit noted that "the Hatch-Waxman framework presents a different set of circumstances than those which underlie an ordinary infringement action." App. 24a. In most situations, the panel majority reasoned, the competitor of a patent holder can enter the market freely, but under Hatch-Waxman market entry must be authorized by the FDA. *See* 21 U.S.C. § 355(a). Thus, according to the panel, any action which contributes to "preventing the FDA from approving the ANDAs of generic drug manufacturers . . . . is a sufficient Article III injury-in-fact." App. 24a-25a.

This analysis effectively created a private right of action on the part of subsequent ANDA filers to sue for any action or inaction by a pioneering drug company that contributes to Hatch-Waxman's exclusion of generics from the marketplace while the 180-day exclusivity period for a first ANDA filer has not yet been triggered. But this newly minted, judicially created cause of action hardly resembles the civil action to obtain patent certainty created by Congress. Instead, CAPCs authorize only suits over

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demonstrating injury in fact. *Illinois. Citizens Comm. for Broad. v. FCC*, 515 F.2d 397, 413 (D.C. Cir. 1975) (separate statement by Bazelon, J., explaining why he voted in favor of en banc review). Movement in the lower courts in the direction of that discredited approach should be halted.

actual disputes concerning patent infringement or validity. 35 U.S.C. § 271(e)(5). Hence, once Forest gave Caraco a covenant not to sue, the CAPC right of action was terminated as a constitutionally cognizable controversy. *See infra* n.10. (Validity of the '941 patent was never in play because Caraco never even sought to challenge that patent on invalidity grounds.)

3. Recognizing that the covenant not to sue was problematic for its theory of standing, the Federal Circuit conceded that "[i]f a threat of suit was the *only action* allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case and divest the district court of Article III jurisdiction." App. 34a (emphasis added).[10] But, "in a manner that is unique to the Hatch-Waxman context," Forest injured Caraco because it listed the '941 patent with

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[10] This analytical move also allowed the panel majority to avoid running afoul of a long line of cases holding that the granting of a covenant not to sue for infringement moots a declaratory judgment action to resolve an infringement dispute. *See Apotex, Inc. v. Pfizer, Inc.*, 125 F. App'x 987, 987 (Fed. Cir. 2005) (per curiam); *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1340-41 (Fed. Cir. 2001); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852, 855 (Fed. Cir. 1999); *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1060 (Fed. Cir. 1995), *cert. denied*, 516 U.S. 1093 (1996). Indeed, just the year prior to handing down the decision in this case, the Federal Circuit had held that this line of cases did not depend on the "reasonable apprehension of suit" test disapproved in *MedImmune*. *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346 (Fed. Cir. 2007). Even applying *MedImmune*, *Benitec* reached the same essential conclusion. Yet the decision below did not distinguish, or even cite, *Benitec*.

the FDA and because it granted Caraco a covenant not to sue for infringement. App. 35a.

This ignores the critical fact that the only adverse action cognizable under the CAPC form of action in this case (where Caraco did not pursue a theory of patent invalidity) was a suit for infringement. Any other actions by Forest, no matter how injurious, cannot support standing because only a suit to declare rights in an infringement controversy can support constitutional standing. While Congress provided that the CAPC action should be interpreted as broadly as possible consistent with the bounds of Article III, *see* 35 U.S.C. § 271(e)(5), the Federal Circuit erred in converting that interpretive instruction into an authorization to create a freestanding cause of action for any injury experienced by ANDA filers traceable in any respect to the blocking patent holder.

4. The only way the panel's decision here could be correct is if injury "in the air" were sufficient to support Article III jurisdiction. It is not. *In re Asbestos Litig.*, 90 F.3d 963, 1020 & n. 70 (5th Cir. 1996) (Smith, J., dissenting) ("[S]tanding analysis does not operate in a vacuum: The allegation of a cause of action frames the inquiry . . . . we must examine the pleadings to determine what cause of action the plaintiff has alleged and whether his allegations of injury, in the context of that cause of action, satisfy Article III standards.").[11] *See also*

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[11] The petition for certiorari was granted in *In re Asbestos Litigation*, with the decision being vacated and remanded for reconsideration on statutory grounds in light of *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997). After remand, reversal by *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), of

International Primate Prot. League v. Administrators of Tulane Educ. Fund, 500 U.S. 72, 77 (1991) ("[S]tanding is gauged by the specific common-law, statutory or constitutional claims that a party presents."); *Catholic Social Serv. v. Shalala*, 12 F.3d 1123, 1125 (D.C. Cir. 1994) (similar); *Lujan*, 504 U.S. at 580 (Kennedy, J., concurring) ("In my view, Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before . . . .").

5. The decision below also is in conflict with the Federal Circuit's prior decisions. *See Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1340-41 (Fed. Cir. 2007) (party that held insufficient rights in a patent lacked standing to sue because "[the plaintiff] is not the party to which the statutes grant judicial relief . . . . [the plaintiff] suffers no legal injury in fact to the patent's exclusionary rights.") (citing *Warth*); *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1308 (Fed. Cir. 2003) (plaintiff lacked Article III standing because it had insufficient legal interest in the patent to be considered "the patentee" under the Patent Act). Indeed, the author of this very opinion previously recognized that standing can only be founded upon the assertion of a viable cause of action. *Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1346 (Fed. Cir. 2001) (Gajarsa, J.) (relying on *Lujan*, stating "TCI-California is correct in its assertion that Article III standing to sue in this case derives solely from

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the Fifth Circuit majority, fully vindicated the pre- and post-remand dissents of Judge Smith, albeit on grounds of a lack of "statutory standing." *Id.* at 831.

the Patent Act.").

In like manner, in a decision released just this September addressing a fact pattern very similar to this case, a *different* panel of the Federal Circuit appeared to recognize, in conflict with the holding here, the absence of a legally cognizable injury. In *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), the innovator pharmaceutical company (Janssen) listed three patents in the Orange Book and successfully defended against challenges brought by the first Paragraph IV ANDA filers to the earliest-expiring patent. *Id.* at 1357-58. In subsequent litigation between the innovator and another generic (Apotex), the generic stipulated that the earliest-expiring patent was valid and not infringed, and the innovator gave the generic a covenant not to sue on the other two patents. *Id.* at 1358-59. In that case, the Federal Circuit held that the generic's declaratory judgment claims with respect to the latter two patents were moot. *Id.* at 1360-61. The court stated that "Apotex's inability to launch its generic . . . because of Teva's 180-day exclusivity period *is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act.*" *Id.* (emphasis added).

The only significant difference between *Janssen* and this case—and the basis on which the *Janssen* panel purported to distinguish this case—is that Forest and Caraco are litigating Forest's earliest-expiring patent on Lexapro—the '712 patent—in a separate action. *Id.* at 1361. In petition-for-rehearing briefing, neither side in the *Janssen* litigation found this distinction entirely tenable. The losing generic company, of course, protested that

the instant case and *Janssen* were indistinguishable. But even prevailing party Janssen, the innovator drug company, argued in the alternative that the Federal Circuit decision here should be overruled in *Janssen* because both this suit and that suit are beyond the reach of Article III. Nevertheless, the Federal Circuit denied Apotex's petition for rehearing on October 29, 2008.

The ineluctable conclusion to be drawn from this cacophony of Federal Circuit precedent is that the court is deeply confused about the protectable-right requirement of *Lujan*, both generally and in the vitally important context of the Hatch-Waxman Act. Even when the Federal Circuit acknowledges the importance of legally protected rights to standing issues, it does not necessarily deploy the correct analysis. *See Willis v. GAO*, 448 F.3d 1341, 1349 (Fed. Cir. 2006) (only client had legally protected right to statutory attorney's fees and hence "the attorney [seeking to recover fees] fails to satisfy the requirements of *prudential standing*") (emphasis added). The emphasis in *McConnell*, *Lujan*, *International Primate*, and *Warth* on legally protected rights was *not* premised on prudential standing. To the contrary, it was premised upon the foundational requirements of Article III.

II. Contrary To Supreme Court And Circuit Law, The Federal Circuit's Decision Finds Standing Where Causation Is Fairly Traceable Only To Causes Beyond The Defendants' Control.

1. The Federal Circuit held that Caraco's injury is "fairly traceable" to Forest because "if Forest had not listed its '712 and '941 patents in the FDA's

Orange Book as valid patents covering the drug described in its NDA for Lexapro, then [the Hatch-Waxman Act] would not independently delay Caraco's ANDA from being approved by the FDA." App. 26a. "Such but-for causation," the court concluded, "is sufficient to satisfy the traceability requirement of Article III standing." *Id.* (citing *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n.26 (1978)).

In the full context of this case, however, the Federal Circuit's reliance on "but-for" causation is in tension with decisions of the Tenth Circuit and D.C. Circuit. *See Bronson v. Swensen*, 500 F.3d 1099 (10th Cir. 2007); *Fulani v. Brady*, 935 F.2d 1324 (D.C. Cir. 1991). Those courts have rejected but-for causation as sufficient to establish standing where, as here, the complained-of conduct leads to injury only by virtue of its combination with other, more dominant causes traceable to sovereign acts.

In *Bronson*, the plaintiffs filed a civil rights action against a county clerk for refusing to issue a marriage license that would have resulted in a polygamous union in violation of state criminal law. 500 F.3d at 1101. Although conceding that the clerk had no power to initiate criminal prosecutions, the plaintiffs argued that their injury was traceable to the county clerk because if the clerk issued a marriage license, then they arguably would be free from fear of criminal prosecution. *Id.* at 1110-11. The Tenth Circuit rejected plaintiffs' arguments because they were based on allegations that they would receive collateral benefits (freedom from criminal prosecution) if the clerk granted the license, not on any injury caused by the clerk. *Id.* at 1111.

Likewise, in *Fulani*, a minor-party presidential

candidate brought an action against the Internal Revenue Service challenging the tax-exempt status of the Commission for Presidential Debates, which had excluded her from the 1988 presidential debates. 935 F.2d at 1325. Under Federal Election Commission rules, the Commission could sponsor the debate only if it received tax-exempt status. *Id.* at 1325, 1330. The D.C. Circuit concluded that Fulani lacked standing to bring her challenge because the "IRS's actions caused her alleged injury only due to other intervening causal factors," including the FEC's regulations and Commission's actions. *Id.* at 1331. Even though Fulani's suit against the IRS, if successful, would have resulted in the Commission no longer being able to hold debates that excluded her as a participant, the D.C. Circuit rejected the argument that because Fulani's injury might be redressed by judgment against the IRS, the IRS must be deemed the cause of her injury.

In this case, by contrast, the Federal Circuit has taken the position that because Caraco's victory in a declaratory judgment suit against Forest could ameliorate Caraco's injury of delay in market entry, Forest's actions to grant a covenant not to sue and its compliance with the Hatch-Waxman Act listing mandate must be the causes of Caraco's injury. But the Federal Circuit's holding that a party's mandatory compliance with a statute can give rise to actionable injury by another party cannot be squared with the judgments of the Tenth and D.C. Circuits. Those courts properly recognize that Article III standing requires that the injury that is the subject of the suit be caused by the defendant that the plaintiff is suing. *Accord Lujan*, 504 U.S. at 560-61 ("[T]here must be a causal connection between the

injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action *of the defendant*, and not . . . th[e] result [of] the independent action of some third party not before the court.'") (emphasis added) (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)).

In *Allen v. Wright*, 468 U.S. 737 (1984), *Simon*, and *Warth*, this Court held that the plaintiffs' injuries were not "fairly traceable" to the defendants where the chain of causation was broken by the actions of independent third parties. In *Allen* and *Simon*, the plaintiffs sued officers of the IRS, alleging that the Service's unlawful grants of tax exemptions to third parties led to the plaintiffs suffering injuries at the hands of the third parties. *See Allen*, 468 U.S. at 746 (explaining the chain of causation alleged in the complaint); *Simon*, 426 U.S. at 32-33 (same). In *Warth*, the plaintiffs alleged that a city's zoning ordinance led to their injury by making it more difficult for third parties to confer benefits on them. 422 U.S. at 495-97.

2. There is simply no basis for concluding that Forest's actions are the real cause of the injury the Federal Circuit posited Caraco suffers—exclusion from the market for generic Lexapro. This is true for several reasons.

First, the primary source of Caraco's inability to sell generic Lexapro is the Hatch-Waxman Act bar blocking the FDA from approving Caraco's ANDA until 180 days after (1) Ivax begins marketing its generic products; or (2) for each patent at issue, issuance of a decision of non-infringement or invalidity. 21 U.S.C. § 355(j)(5)(B)(iv) (2000). That obstacle, however, is not of Forest's making. Rather,

it is the result of Congress's decision to encourage early challenges to patents listed in the Orange Book by rewarding the first generic to file a Paragraph IV certification, which inevitably comes at the expense of subsequent-filer generics. In this case, Ivax was the *first* filer on the '941 patent. Caraco was the *seventh*. Hence, by congressional decree, Caraco must wait until Ivax's exclusivity period has elapsed.

Second, Forest's challenged conduct—the listing of its patents in the Orange Book—is required by statute. 21 U.S.C. § 355(b)(1). Had Forest failed to list either of its patents, it would be subject to various penalties, including withdrawal of its own NDA approval and authorization to sell. *See* 21 U.S.C. § 355(e)(4); 21 C.F.R. § 314.150(a)(2)(v) (1999); 21 C.F.R. § 314.53(b),(c) (2004). Indeed, the Hatch-Waxman listing obligation is backed forcefully by potential criminal sanctions. *See* 21 C.F.R. § 314.53(c)(2)(i)(Q) (2004) (failure to provide an accurate and complete submission of patent information in an NDA subjects the holder to criminal liability for perjury). Thus, to the extent that Forest's listing of its patents caused Caraco's injury, that is the consequence of yet another set of choices made by Congress, or by the FDA pursuant to delegated authority under Hatch-Waxman.

Third, as explained in Section I, *supra*, even if Forest's decision to avoid the expense and disruption of litigation concerning the '941 patent were a minor contributing cause of injury to Caraco, such a cause is not legally actionable. The reason is that Forest has no enforceable duty to refrain from granting irrevocable covenants not to sue and because, on the flip side of that point, Caraco has no valid cause of action to force Forest to retract its covenant.

3. The Federal Circuit majority accuses Forest of "gaming" the Hatch-Waxman Act system. App. 9a. Not so. It is wrong to presume that every decision by a pioneer drug holder to litigate regarding only one of its patents constitutes strategic behavior. Avoiding the costs, uncertainty, and disruption of litigation are legitimate ends in themselves.

Apparently, the court below thought that it was empowered to assume that any action by a pioneer drug company which might contribute to the delay of the introduction of generic competition violated Congress's purposes in enacting Hatch-Waxman and the Medicare Modernization Act amendments. App. 8a (discussing a pioneer drug company's "strong incentive to avoid litigation" so as to delay the onset of a first ANDA filer's exclusivity period).

But "no legislation pursues its purposes at all costs. . . . [I]t frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law." *Rodriguez v. United States*, 480 U.S. 522, 525-526, (1987) (per curiam). The Federal Circuit majority itself recognized this when it pointed out that the purpose of Hatch-Waxman was to *balance* the interests of pioneer and generic drug companies. App. 3a. But by elevating a minor cause and ignoring the more dominant causes of the Hatch-Waxman restriction on market entry and the Act's requirement to list patents in the Orange Book, the majority below took it upon itself to rebalance Congress's policy choices as inherent in the limits on the cause of action for infringement as established in the CAPC form of suit. Or, as dissenting Judge Friedman recognized, "[t]o the extent that Congress may conclude that particular judicial interpretations

of the Act thwart the purposes of the legislation, it is for Congress, not this court, to make whatever changes in the Act it deems appropriate." App. 42a.

III. The Issues In This Case Are Exceptionally Important To Pharmaceutical Innovation And The Nation's Economy.

1. The Federal Circuit's decision threatens to disrupt the careful balance of incentives Congress created to ensure that the public will benefit from receiving the most pharmaceutical innovation at the lowest cost. The divided panel's decision creates a precedent of generalized significance concerning the effect of covenants not to sue on all future CAPC actions under the Hatch-Waxman Act, and thus will apply to all relevant patent disputes in this area. 28 U.S.C. § 1295(a)(1), (a)(4); *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 829 (2002).

The landmark Hatch-Waxman legislation amended both the food and drug and the patent laws to strike a careful balance between two competing policy objectives: (1) inducing innovators to make the investments necessary to develop new drugs, and (2) enabling generics to bring lower-cost versions of those drugs to market in a timely fashion. *See Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 802 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

In furtherance of the latter objective, Congress encouraged generics to challenge innovators' patents as soon as possible by offering the incentive of 180 days of generic market exclusivity to the *first* ANDA

filer. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Importantly, Congress chose to protect the 180-day exclusivity period by forbidding the FDA from approving the applications of other generics. *Id.*

In the case at hand, the panel majority may have chosen to discount the value Congress placed upon incentives to first filers because it had the *ex post* knowledge that Ivax's patent litigation against Forest had failed. But that kind of *post hoc* analysis is improper because the incentives for first filers to bring patent challenges inevitably have to be set *ex ante* behind a veil of ignorance as to whether particular patent litigation will succeed or fail. From a "Monday-morning quarterback" perspective, it is easy to see why a court might want to give a chance to other generics to take their own separate shots at piercing a patent. But it frustrates the will of Congress to do anything other than faithfully and vigorously enforce the 180-day market exclusion the Article I branch established to incentivize first filers to mount patent challenges. *Cf. Hughes Aircraft Co. v. Jacobsen*, 525 U.S. 432, 447 (1999) ("[B]ecause ERISA is a comprehensive and reticulated statute, and is enormously complex and detailed, it should not be supplemented with extratextual remedies.") (citations and internal quotation marks omitted).

In this case, Ivax lunged at the incentive Congress established and assumed the substantial risk of bringing the *first* challenge to Forest's patents. Caraco, by contrast, choose to fall back deep into the queue. It waited a year to become the *seventh* ANDA filer to challenge Forest's '941 patent. Given Ivax's initiative and Caraco's opportunistic choice of waiting to see how infringement litigation between Forest and Ivax played out, Forest's

willingness to avoid further litigation by granting a covenant not to sue, together with the limited cause of action for infringement or invalidity created in the Medicare Modernization Act, add up to the nonexistence of an Article III controversy. In short, no tears should be shed for Caraco. Had it been the first ANDA filer, it would not be in a position where it lacks a viable cause of action and thus constitutional standing.

2. If the Federal Circuit's decision is allowed to stand, it will cause serious marketplace harm, diluting the incentives Congress created for both innovators and first-out-of-the-gate generics.

First, innovators like Forest will be forced to defend themselves in needless litigation against generics they have already promised not to sue. Indeed, the Federal Circuit never considered the practical implications of its holding. Can Forest be conscripted against its will to litigate against Caraco? Does interpreting the statute to have the effect of drafting Forest into an involuntary litigation role raise constitutional questions? Are there interpretations of Hatch Waxman that would avoid such an unprecedented interference in private litigation, in the fashion of *Ashwander v. TVA*, 297 U.S. 288, 348 (1936) (Brandeis, J.) ("[I]t is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the [constitutional] question may be avoided")? No satisfactory answers were provided (or even ventured) to these questions by the Federal Circuit.

Second, the boldest risk-taking generics most favored by Congress, such as Ivax, will witness a severe reduction of their incentives to engage in

costly patent challenges. As it explained in its *amicus* brief in support of rehearing below, "Ivax has a strong interest in protecting the exclusivity incentive against unproductive and self-serving challenges like Caraco's." Br. Amicus Curiae of Ivax Pharm., Inc. in Support of Rehearing at 3. "If generic companies can bring declaratory judgment actions directed to patents that they have no risk of infringing, and by so doing eliminate a competitor's marketing exclusivity, they will do so at every opportunity." *Id.* at 2-3. The serious practical problem, which Congress wisely calibrated the Hatch-Waxman regime to account for, is that a sidelines-sitting opportunist like Caraco has far less "skin in the game" than an incentivized challenger like Ivax.

Indeed, the balance of incentives Congress offered to innovators and generics is critically important to the public interest. In 2007, the American pharmaceutical industry spent an estimated $58.8 billion on research and development of new drugs. *See* Pharmaceutical Research & Manufacturers of America, PHARMACEUTICAL INDUSTRY PROFILE 2 (2008). On the other side of the scales, a 1998 study estimated that generic drugs save consumers between $8 and 10 billion per year. *See* Congressional Budget Office, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 31 (1998). In a poor exchange, the Federal Circuit's decision weakens the incentives in both sectors of the pharmaceutical industry so as to reward laggard generics. This is irrational and contrary to Congress's democratic choices (which are protected by the bulwark of Article III). Most

importantly, in undermining the incentives both to the development of new pioneering drugs and efforts by bold generics to weed out weak patents from the system, the divided panel decision below will inexorably inflict net harm on consumers and the public health.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be granted.

Respectfully submitted,

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November 6, 2008

APPENDIX

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CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff-Appellant,

v.

FOREST LABORATORIES, INC., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S, Defendants-Appellees.

No. 2007-1404.

United States Court of Appeals, Federal Circuit.

April 1, 2008.

Rehearing and Rehearing En Banc Denied June 24, 2008.

James F. Hurst, Winston & Strawn, LLP, of Chicago, IL, argued for plaintiff-appellant. With him on the brief were Derek J. Sarafa and Samuel S. Park. Of counsel on the brief were Steffen N. Johnson and Luke W. Goodrich, of Washington, DC.

Gerald J. Flattmann, Jr., Kirkland & Ellis LLP, of New York, NY, argued for defendants-appellees. With him on the brief were John M. Desmarais, Christine Willgoos, and Benjamin A. Lasky. Of counsel was Peter J. Armenio.

Before GAJARSA, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and PROST, Circuit Judge.

Opinion for the court filed by Circuit Judge GAJARSA. Dissenting opinion filed by Circuit Judge FRIEDMAN.

GAJARSA, Circuit Judge.

This is an action brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the provision of the Hatch-Waxman Act establishing civil actions for patent certainty, 21 U.S.C. § 355(j)(5)(C). Plaintiff-Appellant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") appeals a decision of the United States District Court for the Eastern District of Michigan dismissing its declaratory judgment action for noninfringement against Defendants-Appellees Forest Laboratories, Inc., et al., ("Forest"). Caraco's action was dismissed for lack of Article III jurisdiction on the grounds that it had been rendered moot when Forest unilaterally granted Caraco a covenant not to sue for infringement of the patent-in-suit, U.S. Patent No. 6,916,941. However, in the context of the Hatch-Waxman framework, Forest's covenant not to sue did not eliminate the controversy between the parties. Accordingly, we hold that Caraco's declaratory judgment action presents a continuing Article III controversy, and *reverse* and *remand* for further proceedings.

I. BACKGROUND

This case arises under the Hatch-Waxman Act,[1] which governs the Food and Drug Administration's ("FDA") approval of new and generic drugs. The goal of the Act is to "[strike] a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). The following five aspects of the Hatch-Waxman framework are relevant to this case.

First, a pioneering drug company must obtain FDA approval for its drug by submitting a New Drug Application ("NDA"). *See* 21 U.S.C. § 355(a), (b). As part of the NDA process, the drug company must inform the FDA of all patents covering its drug or the methods of using the drug, "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists all such patents in a publication titled the "Approved Drug Products With Therapeutic Equivalence Evaluations." This publication is commonly known as the "Orange Book." Drugs

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[1] The Hatch-Waxman Act is the name commonly used to refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2000), 35 U.S.C. §§ 156, 271, 282 (2000)), as amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

approved by the FDA are known as "listed drugs." *See* 21 U.S.C. § 355(j)(2)(A)(i).

Second, to facilitate the development of generic versions of listed drugs, the Hatch-Waxman Act provides an Abbreviated New Drug Application ("ANDA") process for generic drug manufacturers. *See* 21 U.S.C. § 355(j). The ANDA process streamlines FDA approval of generic drugs by allowing applicants to rely on the results of the safety and efficacy studies that supported the FDA's approval of a listed drug. *See id.; Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676, 110 S. Ct. 2683, 110 L. Ed.2d 605 (1990). Under the ANDA process, a generic drug company must submit information to show, inter alia, that its generic drug and the relevant listed drug share the same active ingredients and are bioequivalent. 21 U.S.C. § 355(j)(2)(A)(ii), (iv). In addition, generic drug companies must submit one of four certifications addressing each Orange-Book-listed patent covering the listed drug. Specifically, the ANDA filer must certify –

> (I) that [the required] patent information has not been filed [with the FDA],
>
> (II) that such patent has expired,
>
> (III) of the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). If a generic drug company seeks to market a generic version of a listed drug before the expiration of Orange-Book-listed patents covering that drug, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e. a "Paragraph IV certification." *See Eli Lilly*, 496 U.S. at 677, 110 S. Ct. 2683. All Paragraph IV ANDA filers must provide notice of their Paragraph IV certification to both the patent owner and the NDA holder. 21 U.S.C. § 355(j)(2)(B). This notice must set forth a "detailed statement of the factual and legal basis for the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B)(iv)(II).

Third, the Hatch-Waxman Act facilitates the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement. 35 U.S.C. § 271(e)(2); *Eli Lilly*, 496 U.S. at 678, 110 S. Ct. 2683. The Act states that "it shall be an act of infringement" to submit an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2). As this court has explained, "§ 271(e)(2) is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004) (emphasis in original); *see also Eli Lilly*, 496 U.S. at 678, 110 S. Ct. 2683 ("Quite obviously, the purpose of subsection[ ] (e)(2) . . . is to enable the judicial adjudication upon which the ANDA . . . scheme[ ] depend[s].")

Fourth, to incentivize ANDA filers to challenge the validity of listed patents or design around those patents as early as possible, the Hatch-Waxman Act provides that the first ANDA applicant to file a Paragraph IV certification ("first Paragraph IV ANDA filer") shall enjoy a 180-day period of generic marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Until the first Paragraph IV ANDA filer's exclusivity period expires, the FDA may not approve a later-filed Paragraph IV ANDA based on the same NDA (hereinafter a "subsequent Paragraph IV ANDA"). *Id.* Importantly, the first Paragraph IV ANDA filer is entitled to the 180-day exclusivity period whether or not it establishes that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its ANDA; all that is required is that the first Paragraph IV ANDA filer submit a substantially complete ANDA that contains a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

The Hatch-Waxman Act provides that the 180-day period of exclusivity begins either on the date that the first Paragraph IV ANDA filer begins marketing its generic drug, or on the date of a final court decision finding the relevant Orange-Book-listed patents invalid or not infringed, whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000)[2];

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[2] In 2003, Congress replaced the provisions governing the commencement of the 180-day exclusivity period with a new regime under which the first Paragraph IV ANDA filer can forfeit its exclusivity period if it fails to market its drug within a certain time. *See* 21 U.S.C. § 355(j)(5)(D); *see also Pfizer*, 395 F.3d at 1329. The amendment was part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("Medicare

see also Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1328 (Fed. Cir. 2005) ("*Pfizer*"). In other words, the applicable statutory provisions provide for two methods of triggering the first Paragraph IV ANDA filer's 180-day exclusivity period: (1) a commercial-marketing trigger pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000) and (2) a court-judgment trigger pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Only the first Paragraph IV ANDA filer can trigger its 180-day exclusivity period via the commercial-marketing trigger. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I). However, subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger. *Minn. Mining & Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 780 (Fed. Cir. 2002) ("*3M*") (holding that the first Paragraph IV ANDA filer's 180-day exclusivity period can be triggered by a court judgment obtained by a subsequent Paragraph IV ANDA filer).

Modernization Act" or "MMA"), which was enacted on December 8, 2003. *Pfizer*, 395 F.3d at 1328-29. Despite these changes, the MMA contained a grandfather provision specifying that the amendments do not apply to Paragraph IV ANDAs filed before the date of enactment of the MMA. *See* MMA § 1102(b). The amendments also do not apply if another generic drug company had filed a Paragraph IV ANDA for the same listed drug before the date of enactment of the MMA. *Id.* In this case, a generic drug company, namely Ivax Pharmaceuticals, Inc., filed a Paragraph IV ANDA in August 2003, before the December 2003 enactment of the MMA. Thus, the MMA amendments to the provisions governing the commencement of 180-day exclusivity period are inapplicable to this case.

Since the FDA cannot approve subsequent Paragraph IV ANDAs until the first Paragraph IV ANDA filer's 180-day exclusivity period expires, the date on which the exclusivity period is triggered is critical to NDA holders and subsequent Paragraph IV ANDA filers. On the one hand, subsequent Paragraph IV ANDA filers have a strong incentive to generate a triggering event allowing the FDA to approve their subsequent Paragraph IV ANDAs 181 days after the triggering event. On the other hand, NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be approved until the exclusivity period expires. Moreover, because subsequent Paragraph IV ANDA filers can only activate the first Paragraph IV ANDA filer's 180-day exclusivity period through the court-judgment trigger, subsequent Paragraph IV ANDA filers have a strong incentive to challenge the NDA holder's Orange-Book-listed patents in court. Conversely, NDA holders have a strong incentive to avoid litigation that would trigger the first Paragraph IV ANDA filer's exclusivity period and allow the FDA to approve subsequent Paragraph IV ANDAs 181 days after the triggering event.

For example, if a first Paragraph IV ANDA filer is found liable in a § 271(e)(2) infringement action or simply fails to market its generic drug, then it has not triggered its own exclusivity period through the court-judgment trigger or the commercial-marketing trigger. In that case, a subsequent Paragraph IV ANDA filer must generate a court-judgment triggering event in order to activate the first Paragraph IV ANDA filer's 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000); *3M*, 289 F.3d at 780. More precisely, the subsequent

Paragraph IV ANDA filer must obtain a judgment that the NDA holder's Orange-Book-listed patents are invalid or not infringed by the drug described in its subsequent Paragraph IV ANDA. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). However, if the NDA holder can prevent the subsequent Paragraph IV ANDA filer's court challenge, it can delay FDA approval of the subsequent Paragraph IV ANDA and thus delay the subsequent Paragraph IV ANDA filer's entry into the market. *See* 21 U.S.C. § 355(a) (providing that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an [NDA or ANDA] is effective with respect to such a drug") Indeed, an NDA holder could thus delay any subsequent Paragraph IV ANDA filer from entering the market until the NDA holder's Orange-Book-listed patents expire.[3]

The fifth and final aspect of the Hatch-Waxman Act relevant to this case is the "civil action to obtain patent certainty" ("CAPC"). *See* 21 U.S.C. § 355(j)(5)(C). The CAPC is designed to prevent NDA holders from "gaming" the Hatch-Waxman Act by forestalling the resolution of patent disputes with ANDA filers. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342 (Fed. Cir. 2007) ("*Novartis*"). Under the CAPC provisions, if the NDA holder fails to sue a Paragraph IV ANDA filer within 45 days, the ANDA filer can sue the NDA

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[3] Generic drug companies can obtain immediate FDA approval of their drugs when the relevant Orange-Book-listed patents expire by submitting a Paragraph III ANDA certifying that the patents will expire on that date. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).

holder to obtain a declaratory judgment that the relevant Orange-Book-listed patents are invalid or not infringed. 21 U.S.C. § 355(j)(5)(C).

In addition, Congress extended federal jurisdiction over CAPCs "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Accordingly, federal courts have jurisdiction over CAPCs to the extent that they present an Article III case or controversy. *Novartis*, 482 F.2d at 1342. Congress explained the need for broad federal jurisdiction over CAPCs as follows:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.[4]

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[4] The discussion here refers to the "failure to market" provision of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(D), under which the first Paragraph IV ANDA filer can forfeit its 180-day exclusivity period by failing to market its generic drug. Section 355(j)(5)(D) replaced the 180-day exclusivity period triggering provisions that are applicable to this case, i.e. 21 U.S.C. § 355(j)(5)(B)(iv) (2000), including the court-judgment trigger. *See supra* note 2 (discussing MMA § 1102(b), 117 Stat. at 2460). Although the legislative discussion here refers to the amended 180-day provisions, this distinction is inconsequential because under both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed. Thus, Senator Kennedy's remarks

> In . . . these . . . circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period. *We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes.* The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions) (emphasis added).

II. FACTS

A. Forest's NDA for Lexapro®

Forest holds an approved NDA for its drug Lexapro®, which is used to treat depression and generalized anxiety disorder. Forest currently faces no generic competition for Lexapro®. *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 438 F. Supp. 2d 479, 494 (D. Del. 2006).

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concerning the brand name drug company's incentive to delay such court decisions are equally applicable to this case.

As part of the process for filing its Lexapro® NDA, Forest listed two patents in the FDA's Orange Book, namely: U.S. Patent Nos. Re. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). The '712 patent includes claims covering substantially pure forms of escitalopram, the active ingredient of Lexapro®. The '941 patent generally covers crystalline particles of escitalopram oxate of a particular size range, as well as dosage forms containing particles of this size range, and methods of manufacturing particles in this size range. The '712 patent expires in 2012; the '941 patent expires in 2023.

B. The First Paragraph IV Challenge to Forest's Orange-Book-Listed Patents for Lexapro® and the Consequences for Subsequent Paragraph IV ANDA Filers

The first ANDA applicant to file a Paragraph IV certification for Forest's '712 and '941 patents was Ivax Pharmaceuticals, Inc. ("Ivax"). Accordingly, Ivax is entitled to 180 days of generic market exclusivity, which will begin either on the day it begins marketing its generic drug, or on the date a court determines that the '712 and '941 patents are invalid or not infringed – whichever comes first. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

Forest responded to Ivax's Paragraph IV ANDA by suing Ivax for infringement of the '712 patent, the earlier of the two patents to expire. Ivax counterclaimed that the '712 patent was invalid. Despite suing Ivax on the '712 patent, Forest did not sue Ivax for infringement of the '941 patent. By holding the '941 patent in reserve, Forest insulated

itself from an invalidity or noninfringement challenge by Ivax.[5] Ultimately, Forest defeated Ivax's counterclaim of invalidity on the '712 patent and obtained a judgment that the drug described in Ivax's ANDA infringed the '712 patent, which was affirmed by this court in *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263 (Fed. Cir. 2007).

In sum, after filing a Paragraph IV certification for both the '712 and '941 patents in its ANDA, Ivax failed to obtain a court judgment that either the '712 or the '941 patent is invalid or not infringed by the drug described in its ANDA. Because Ivax has not obtained a judgment that both of Forest's Orange-Book-listed patents are invalid or not infringed by the generic drug described in its ANDA, Ivax failed to trigger its 180-day exclusivity period via the court-judgment trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000).

In addition, because the generic drug described in Ivax's ANDA was found to infringe the '712 patent, Ivax cannot trigger its 180-day exclusivity period via the commercial-marketing trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000), until the '712 patent

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[5] As will be discussed in more detail later, in *Novartis* this court held that where an NDA holder brings an infringement suit against a Paragraph IV ANDA filer on only one of several Orange-Book-listed patents covering its NDA, the ANDA filer has standing to seek a declaratory judgment on any of the NDA holder's remaining Orange-Book-listed patents for that NDA. 482 F.2d at 1346. However, *Novartis* had not been decided at the time of Forest and Ivax's dispute, and in any case, Ivax never sought a declaratory judgment that Forest's '941 patent was invalid or not infringed by its generic drug, *see Ivax Pharms., Inc.*, 501 F.3d at 1265.

expires in 2012. Indeed, the district court specifically enjoined Ivax from "making, using, offering to sell or selling within the United States, or importing into the United States any products that infringe the '712 patent, including the [drug] products referred to in [Ivax's ANDA] until such time as the '712 patent expires . . . ." *Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF (D. Del. Nov. 3, 2006) (Judgment Order). As a result, Ivax cannot activate its exclusivity period via the commercial-marketing trigger until the '712 patent expires.

With Ivax no longer able to trigger its exclusivity period, only two pathways remain open to subsequent Paragraph IV ANDA filers who seek to trigger Ivax's exclusivity period before the '712 patent expires in 2012. First, a subsequent Paragraph IV ANDA filer could obtain a court judgment invalidating the '712 patent, which would allow the FDA to approve Ivax's drug. With FDA approval, Ivax would be legally free to sell its generic drug, and its exclusivity period would be triggered on the day of its first commercial marketing. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I) (2000) (the "commercial-marketing trigger"). Second, a subsequent Paragraph IV ANDA filer could trigger Ivax's exclusivity period immediately—regardless of when Ivax begins marketing its drug—via the court-judgment trigger, 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). However, because Ivax was the first Paragraph IV ANDA filer with respect to both the '712 and '941 patents, a subsequent Paragraph IV ANDA filer can only activate Ivax's exclusivity period via the court-judgment trigger by obtaining a judgment that both the '712 and '941 patents are invalid or not infringed.

If a subsequent Paragraph IV ANDA filer is not able to pursue either of these two pathways to triggering Ivax's exclusivity period, then Ivax's exclusivity period cannot begin until the '712 patent expires in 2012. Moreover, assuming there has been no other triggering event by that time, Ivax's exclusivity period will not be triggered on the date the '712 patent expires unless Ivax actually begins marketing its generic drug on that date. Even if Ivax does so, the FDA will still be restricted from approving any subsequent Paragraph IV ANDA until 181 days after the date the '712 patent expires.[6] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

In short, absent an event triggering Ivax's exclusivity, all subsequent Paragraph IV ANDA filers, including Caraco, will be denied entry to the drug market for a significant time. These subsequent Paragraph IV ANDA filers will be precluded from the market regardless of whether the generic drugs described in their ANDAs infringe Forest's Orange-Book-listed patents and regardless of whether Forest's patents are valid.

C. Caraco's Subsequent Challenge to Forest's Orange-Book-Listed Patents for Lexapro®

In May 2006, Plaintiff-Appellant Caraco filed an ANDA for generic escitalopram that included a

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[6] When the '712 patent expires, subsequent Paragraph IV ANDA filers will not be able to obtain immediate FDA approval by filing a Paragraph III certification; obtaining FDA approval by filing a Paragraph III certification will not be an option until Forest's other Orange-Book-listed patent covering Lexapro®, the '941 patent, expires in 2023. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).

Paragraph IV certification for Forest's '712 and '941 patents for Lexapro®. Under 35 U.S.C. § 271(e)(2), this constituted a technical act of infringement of both patents. Forest sued Caraco for infringement of the '712 patent in a lawsuit filed in the Eastern District of Michigan, *Forest Labs., Inc., v. Caraco Pharm. Labs., Ltd.*, Case No. 2:06-EV-13143-BAF-MKM.[7] As of the time of this writing, the parties' litigation with respect to the '712 patent is ongoing.

Despite suing Caraco for infringement of the '712 patent, Forest did not sue Caraco on the '941 patent. However as discussed above, under the Hatch-Waxman framework Caraco has an economic interest in determining whether the '941 patent is invalid or not infringed by the drug described in its ANDA, because only a judgment of invalidity or noninfringement with respect to both the '712 and '941 patents can trigger Ivax's exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Accordingly, Caraco filed a separate action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the Hatch-Waxman provision establishing the CAPC, 21 U.S.C. § 355(j)(5)(C), seeking a declaratory judgment that the drug described in its ANDA does not infringe Forest's '941 patent. Caraco's

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[7] It should be noted that by suing Caraco for infringement of the '712 patent, Forest triggered the automatic 30-month stay of FDA approval provided in 21 U.S.C. § 355(j)(5)(B)(iii). Under § 355(j)(5)(B)(iii), "[i]f the patentee files an infringement action within forty-five days after receiving notice of the paragraph IV certification, an automatic thirty-month "stay" goes into effect, during which the FDA cannot approve the ANDA unless the suit is resolved or the patent expires." *Pfizer*, 395 F.3d at 1328.

declaratory judgment action with respect to the '941 patent is the case presently on appeal.

Shortly after Caraco sued Forest for a declaratory judgment on the '941 patent, Forest filed a motion to dismiss Caraco's action pursuant to Fed. R. Civ. P. 12(b)(1) on the grounds that the action did not present a "case" or "controversy" as required by Article III of the Constitution. In its motion, Forest argued that there was no controversy because Caraco did not have a reasonable apprehension of suit on the '941 patent. At the time Forest filed its motion, this court's most recent precedent governing the justiciability of declaratory judgment suits applied the reasonable-apprehension-of-suit test to determine whether a justiciable controversy existed. *See, e.g.*, *Pfizer*, 395 F.3d at 1332. However, as is discussed in more detail below, even before Forest filed its motion, the Supreme Court found the reasonable-apprehension-of-suit test inconsistent with its precedent. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, n.11, 127 S. Ct. 764, 774 n.11, 166 L. Ed. 2d 604 (2007). The Court explained in *MedImmune* that whether a declaratory judgment action presents an Article III controversy must be determined based on "all the circumstances," not merely on whether the declaratory judgment plaintiff is under a reasonable apprehension of suit. *Id.* at 771.

In addition, after Forest filed its motion to dismiss but before the district court made its ruling, this court issued its decision in *Novartis*, 482 F.3d 1330. As in the present case, the issue in *Novartis* was whether a Paragraph IV ANDA filer's declaratory judgment action against an NDA holder presented a justiciable Article III case or

controversy. *Id.* at 1335. In *Novartis*, Teva Pharmaceuticals USA, Inc. ("Teva") was the first ANDA applicant to file a Paragraph IV certification on all five Orange-Book-listed patents covering an FDA approved drug owned by Novartis Pharmaceuticals Corp. ("Novartis"). *Id.* at 1334. Although Teva had filed a Paragraph IV certification for all five of Novartis' Orange-Book-listed patents, Novartis only brought suit under 25 U.S.C. § 271(e)(2)(A) for infringement of one of those patents.[8] *Id.*

After Novartis filed suit, Teva brought a separate action against Novartis on the four remaining Orange-Book-listed patents. *Id.* at 1335. However, the district court dismissed Teva's declaratory judgment action for lack of a justiciable controversy on the grounds that Teva had no reasonable apprehension of suit on the four remaining Orange-Book-listed patents. *Id.* This dismissal was the subject of the appeal in *Novartis*. *Id.* On appeal, the court observed that the Supreme Court's *MedImmune* decision had abrogated the reasonable-apprehension-of-suit test, *Novartis*, 482 F.3d at 1339, and applying the Supreme Court's all-the-circumstances test, the court found that there was a justiciable controversy between the parties, *Id.* at 1346. In reaching this decision, the court held that—

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[8] Even though Novartis only sued Teva on one of its Orange-Book-listed patents, this was sufficient to trigger a 30-month stay barring Teva's ANDA from approval under 21 U.S.C. § 355(j)(5)(B)(iii). *Novartis*, 482 F.3d at 1340 n.5.

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

Id. at 1344.

In thus applying the all-the-circumstances test to a declaratory judgment action between an ANDA filer and a pharmaceutical patentee, the *Novartis* decision eliminates Forest's argument that Caraco's declaratory judgment action should be dismissed because Caraco had no reasonable apprehension of suit on the '941 patent. After the *Novartis* decision issued, Forest unilaterally granted Caraco an irrevocable covenant not to sue for infringement of the '941 patent. Forest's stated goal in granting the covenant to Caraco was "to confirm" that there was no case or controversy between the parties regarding the '941 patent. Forest's covenant provides, in relevant part:

> [Forest] hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged

> infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use, sale, offer for sale or importation of the generic products described by ANDA 78-219.

Notably, despite giving Caraco this covenant not to sue, Forest refused to concede that the '941 patent was invalid or not infringed by the drug described in Caraco's ANDA. In fact, Forest hinged its entire argument for dismissal on the covenant not to sue, stating: "There is no controversy because we gave a covenant not to sue." The district court agreed, stating from the bench that "[t]here's a covenant not to sue on the '941 so there's not going to be any loss, *there's no threat of lawsuit*." Transcript of Hearing on Motion to Dismiss at 31 (May 30, 2007) (emphasis added). On this basis, the district court ruled that there was no Article III controversy and granted Forest's motion to dismiss. Notably, there is no indication in the record that the district court considered either the Supreme Court's *MedImmune* decision or this court's *Novartis* decision when making this ruling.

III. ANALYSIS

A district court's dismissal of a declaratory judgment action for lack of jurisdiction presents a question of law that this court reviews de novo. *Novartis*, 482 F.3d at 1335.

Our starting point in analyzing Caraco's appeal is the Declaratory Judgment Act, 28 U.S.C. § 2201(a), under which Caraco filed this suit. The relevant text of the Act provides:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a). It is well established that the phrase "actual controversy" in § 2201(a) includes any controversy over which there is Article III jurisdiction. *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40, 57 S. Ct. 461, 81 L. Ed. 617 (1937) (noting that "the word 'actual' is one of emphasis rather than of definition"). In addition, with respect to declaratory judgment actions brought by Paragraph IV ANDA filers against NDA holders to establish noninfringement or invalidity of Orange-Book-listed patents, Congress has specifically granted federal courts subject matter jurisdiction "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Thus, federal courts have subject matter jurisdiction over such actions to the extent that they present an Article III case or controversy. *See Novartis*, 482 F.3d at 1337.

In *MedImmune*, the Supreme Court reaffirmed the proper standard for determining whether a declaratory judgment action satisfies the Article III case or controversy requirement. 127 S. Ct. at 771. Specifically, the Court framed the justiciability inquiry as "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.*

(quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273, 61 S. Ct. 510, 85 L. Ed. 826 (1941)). In addition, the Supreme Court emphasized that Article III requires that the dispute be "'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Id.* (quoting *Aetna Life Ins.*, 300 U.S. at 240-41).

In *Novartis* this court held that we must "follow *MedImmune's* teaching to look at 'all the circumstances' to determine whether [an action for a declaratory judgment of noninfringement or patent invalidity presents] a justiciable Article III controversy." 482 F.3d at 1339. Accordingly, *Novartis* acknowledged that this court's reasonable-apprehension-of-suit test was overruled by *MedImmune*. *Id.*; *see also SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380 (Fed. Cir. 2007). The reasonable-apprehension-of-suit test required "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity." *Novartis*, 482 F.3d at 1339. Following *MedImmune*, proving a reasonable apprehension of suit is only one of many ways a patentee can satisfy the Supreme Court's more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy.

In applying the all-the-circumstances test to Caraco's declaratory judgment action, we are guided by the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy. In particular, an action is justiciable under Article III only where (1) the plaintiff has standing, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992), (2) the issues presented are ripe for judicial review, *Abbott Labs. v. Gardner*, 387 U.S. 136, 149, 87 S. Ct. 1507, 18 L. Ed. 2d 681 (1967), and (3) the case is not rendered moot at any stage of the litigation, *United States Parole Comm'n. v. Geraghty*, 445 U.S. 388, 397, 100 S. Ct. 1202, 63 L. Ed. 2d 479 (1980). For the following reasons, we hold that Caraco's declaratory judgment action satisfies these requirements and presents a justiciable Article III controversy.

A. Standing

The Supreme Court has explained that the "irreducible constitutional minimum of standing" contains the following three requirements:

> First and foremost, there must be alleged (and ultimately proved) an "injury in fact"—a harm suffered by the plaintiff that is "concrete" and actual or imminent, not "conjectural" or "hypothetical." Second, there must be causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability—a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102-03, 118 S. Ct. 1003, 140 L. Ed. 2d 210 (1998) (internal citations omitted).

1. Caraco Alleges a Judicially Cognizable Injury-in-Fact

In this case, as in most declaratory judgment actions in the patent context, Caraco's alleged injury-in-fact is a "restraint on the free exploitation of non-infringing goods," *Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998). Here, Caraco alleges it is being excluded from selling a non-infringing product because Forest has taken actions that delay the FDA from approving Caraco's ANDA. *See Novartis*, 482 F.3d at 1340 (observing that an ANDA filer suffers the requisite injury-in-fact where its ability to secure approval of its ANDA has been prevented by an NDA holder).

As this court explained in *Novartis*, the Hatch-Waxman framework presents a different set of circumstances than those which underlie an ordinary infringement action: "Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer . . . is not legally free to enter the market [without FDA approval]." 482 F.3d at 1345. Indeed, 21 U.S.C. § 355(a) provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an [NDA or ANDA] is effective with respect to such a drug." Thus, by preventing the FDA from approving the ANDAs of generic drug manufacturers, pharmaceutical patentees like Forest can potentially exclude non-infringing generic

drugs from the market. If Caraco is correct that its generic drug does not infringe Forest's '941 patent, then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions is a sufficient Article III injury-in-fact. Moreover, the fact that Forest's actions can only exclude Caraco from the drug market in the context of the Hatch-Waxman framework does not render Caraco's injury any less "concrete, actual or imminent." *Steel Co.*, 523 U.S. at 102-03.

In sum, Caraco alleges that it has been "restrain[ed from] the free exploitation of non-infringing goods," *Red Wing Shoe*, 148 F.3d at 1360. This is exactly the type of injury-in-fact that is sufficient to establish Article III standing under our caselaw. *See id.*; *see also Novartis*, 482 F.3d at 1345 (explaining that an NDA holder's use of an Orange-Book-listed patent to exclude a generic drug maker from the market creates "the exact type of uncertainty of legal rights that the ANDA declaratory judgment action [i.e. the CAPC, 21 U.S.C. § 355(j)(5)(C)] was enacted to prevent").[9]

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[9] Even before the *MedImmune* and *Novartis* decisions, the District of Columbia Circuit came to a similar conclusion. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998). In *Mova*, the court made the following observation:

> [T]he Federal Circuit has had no occasion to decide whether there is "a controversy of sufficient immediacy and reality" to support a declaratory judgment action, when the plaintiff requires a judgment under section 355(j)(5)(B) in order to bring its product to market. It is possible that such a statutorily-created bottleneck, coupled with the statute's

2. Caraco's Injury Is Traceable to Forest

Caraco's injury is also "fairly traceable [to] the complained-of conduct of the defendant," *Steel Co.*, 523 U.S. at 102-03. It is not the Hatch-Waxman Act or the FDA framework that prevents Caraco's ANDA from being approved by the FDA, but rather Forest's actions in the context—i.e. "under all the circumstances," *MedImmune*, 127 S. Ct. at 771—of the Hatch-Waxman framework. Simply put, if Forest had not listed its '712 and '941 patents in the FDA's Orange Book as valid patents covering the drug described in its NDA for Lexapro®, then 21 U.S.C. § 355(j)(5)(B)(iv) (2000) would not independently delay Caraco's ANDA from being approved by the FDA. Such but-for causation is sufficient to satisfy the traceability requirement of Article III standing. *See Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n.26, 98 S. Ct. 2620, 57 L. Ed. 2d 595 (1978).

As discussed above, where the first Paragraph IV ANDA filer has failed to trigger its own 180-day exclusivity period, the NDA holder's listing of Orange-Book patents delays a subsequent Paragraph IV ANDA filer from entering the marketplace indefinitely. Moreover, this delay occurs even if the drug described in the subsequent

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> express reference to declaratory judgment actions as a means of relieving that bottleneck, might suffice to allow a plaintiff to show the existence of a "case or controversy" without demonstrating an immediate risk of being sued.

Id. (internal citation omitted).

Paragraph IV ANDA does not infringe the Orange-Book-listed patents. Here, Forest's listing of the '712 and '941 patents in the Orange-Book effectively denies Caraco an economic opportunity to enter the marketplace unless Caraco can obtain a judgment that both those patents are invalid or not infringed by its generic drug. Under these circumstances, Forest's listing of the '941 patent (the patent-in-suit) in the Orange-Book creates an independent barrier to the drug market that deprives Caraco of an economic opportunity to compete. It is well established that the creation of such barriers to compete satisfies the causation requirement of Article III standing. *See, e.g., Ne. Fla. Chapter, Associated Gen. Contractors of Am. v. Jacksonville*, 508 U.S. 656, 666, 113 S. Ct. 2297, 124 L. Ed. 2d 586 (1993) (holding that the "imposition of [a] barrier" to bid for certain government contracts satisfied the injury-in-fact and causation requirements of Article III standing); *Clements v. Flashing,* 457 U.S. 957, 962, 102 S. Ct. 2836, 73 L. Ed. 2d 508 (1982) (holding that the imposition of an "obstacle to [plaintiff's] candidacy for higher judicial office" satisfied the injury-in-fact and causation requirements of Article III standing); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 124-25, 89 S. Ct. 1562, 23 L. Ed. 2d 129 (1969) (holding that the plaintiff had standing to sue where it alleged that it had been denied a share of the market).

3. Caraco's Injury Is Redressible by a Favorable Judgment

Finally, Caraco's injury-in-fact is redressible by a declaratory judgment that the '941 patent is not

infringed.[10] A favorable judgment in this case would clear the path to FDA approval that Forest's actions would otherwise deny Caraco—namely, using the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000) to activate Ivax's exclusivity period. If Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent, then it will only need a judgment of invalidity or noninfringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as swiftly as possible. Thus, a favorable judgment in this action would eliminate the potential for the '941 patent to exclude Caraco from the drug market.[11]

* * *

In sum, Caraco's declaratory judgment action satisfies the injury-in-fact, causation, and redressibility requirements of standing. Moreover, even beyond satisfying the requirements of Article III standing, Caraco's action is consistent with the basic purpose of the Declaratory Judgment Act. As this court has previously explained, "the purpose of

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[10] Caraco's injury-in-fact would also be redressed by a judgment that the '941 patent is invalid, but Caraco has not sought a judgment of invalidity in this case.

[11] Although we do not so decide, it appears that if Forest would submit to a consent decree that the drug described in Caraco's ANDA does not infringe the '941 patent, such a decree would redress Caraco's alleged injury-in-fact just as well as any other court judgment. Thus, if Forest's objective in granting the covenant not to sue on the '941 patent was to avoid costly litigation with Caraco, this might be the best approach to resolve the controversy between the parties.

the Declaratory Judgment Act . . . in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987); *see also Novartis*, 482 F.3d at 1336 n.2 ("The Declaratory Judgment Act and 35 U.S.C. § 271(e)(5) 'serve[] the policies underlying the patent laws by enabling a test of the validity and infringement of patents that are . . . being used only as . . . scarecrows.'" (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem*, 846 F.2d 731, 735 (Fed. Cir. 1988))).

In claiming that it has been denied the right to sell non-infringing generic drugs, Caraco has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy. *See Goodyear Tire & Rubber Co.*, 824 F.2d at 956; *Red Wing Shoe*, 148 F.3d at 1360; *see generally* E. Borchard, *Declaratory Judgments* 803-04 (2d ed. 1941) (discussing the history of the Declaratory Judgment Act). In particular, Caraco alleges that Forest's actions exclude it from the market without ever subjecting Forest's '941 patent to a court determination of its scope.[12] Caraco essentially argues that Forest's actions may allow it to "use a restricted [i.e. narrowly drafted] patent to justify much wider claims of infringement," E. Borchard, *supra*, at 803-04. Indeed, Caraco claims that it is being excluded from the drug market by Forest's '941 patent even though the generic drug described in its ANDA may not infringe the '941 patent.

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[12] As noted earlier, in the present action Caraco does not seek a judgment that the '941 patent is invalid.

Finally, Caraco's declaratory judgment action is also consistent with the basic goal of the Hatch-Waxman Act, which is to balance the need for pharmaceutical innovation with the need for generic drug competition. *Andrx Pharms., Inc.*, 276 F.3d at 1371. As previously noted, a significant part of this carefully crafted dialectic balance is encouraging the early resolution of patent disputes when subsequent Paragraph IV ANDA filers are "blocked by a first generic applicant's 180-day exclusivity." *See* 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy).[13]

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[13] Both the dissent and Forest contend that the legislative history of the Hatch-Waxman Act supports the argument that the covenant not to sue moots any and all controversy with Caraco. The legislative history to which the dissent and Forest cite are the following remarks by Senator Edward Kennedy:

> We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a Paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. *We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.*

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions) (emphasis added).

B. Ripeness

Whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.*, 387 U.S. at 149, 87 S. Ct. 1507. As to the first prong, an action is fit for judicial review where further factual development would not "significantly advance [a court's] ability to deal with the legal issues presented." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 812, 123 S. Ct. 2026, 155 L. Ed. 2d 1017 (2003). As to the second prong, withholding court consideration of an action causes hardship to the plaintiff where the complained-of conduct has an "immediate and substantial impact" on the plaintiff. *Gardner v. Toilet Goods Ass'n*, 387

Despite the arguments of the dissent and Forest, Senator Kennedy's remarks regarding the effect of a covenant not to sue were made when this court applied a "reasonable-apprehension-of-suit" test as the sole test for whether an action seeking a declaratory judgment of invalidity or noninfringement presented a justiciable Article III controversy. *See, e.g., Pfizer*, 395 F.3d at 1332. Under the reasonable-apprehension-of-suit test, a covenant not to sue would eliminate the controversy between the parties because the generic drug applicant would no longer have a reasonable apprehension of suit by the patentee. However, as discussed earlier, this singular approach to the justiciability of declaratory judgment actions was struck down by the Supreme Court in *MedImmune*, 127 S. Ct. at 774 n.11. Given this background, Senator Kennedy's comments only emphasize Congress's intent that the jurisdiction of federal courts to resolve CAPCs would extend to the limits of the Constitution. 35 U.S.C. § 271(e)(5). Moreover, it is ultimately the province and duty of the judicial department, not Congress, to discern the limits of Article III jurisdiction. *See Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177, 2 L. Ed. 60 (1803).

U.S. 167, 171, 87 S. Ct. 1526, 18 L. Ed. 2d 704 (1967).

In this case, both prongs of the ripeness inquiry are satisfied. First, additional factual development would not advance the district court's ability to decide Caraco's action for a declaratory judgment of noninfringement. Caraco has a complete generic drug product that has been submitted to the FDA for approval, and no additional facts are required to determine whether this drug product infringes the claims of Forest's '941 patent. Second, if Caraco's drug does not infringe Forest's '941 patent, then withholding court consideration of Caraco's declaratory judgment action has the "immediate and substantial impact" of forestalling Caraco's ability to activate Ivax's exclusivity period through the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000).[14] As noted earlier, only a judgment of

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[14] The dissent concludes that delaying resolution of this suit will have no immediate and substantial impact on Caraco. Indeed, the dissent states that the majority opinion "is highly speculative and conjectural, and involves uncertain legal issues that have not yet been resolved." With all due respect, we disagree. The dissent offers three main reasons to support its conclusion, and we will address each in turn.

First, the dissent states that there is "no basis to conclude that the first-filing generic manufacturer will, or is likely to, delay bringing its product to market after the '712 patent expires." We agree. What the dissent fails to recognize, however, is that the injury upon which Caraco's suit is premised is the delay (in triggering Ivax's exclusivity period) between now and when the '712 patent expires in 2012, not any delay (in triggering Ivax's exclusivity period) after the '712 patent expires. Thus, the dissent is in error when it notes that our analysis requires speculating as to when Ivax decides to market its drug after the '712 patent expires.

invalidity or noninfringement with respect to both the '712 and '941 patents can trigger Ivax's exclusivity period pursuant to 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Thus, if Caraco's drug does not infringe Forest's '941 patent, then delaying court consideration of Caraco's declaratory judgment action on the '941 patent delays the date on which the FDA is authorized to approve Caraco's ANDA. Specifically, Caraco would be delayed until at least 181 days after the '712 patent expires in 2012. Because Caraco cannot market its generic drug without FDA approval, being delayed from resolving its claim to noninfringement of the '941 patent

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Second, the dissent states that we assume that a first Paragraph IV ANDA filer who unreasonably delays in marketing its drug cannot lose its right to exclusivity. The dissent is incorrect. Our conclusion that the first filer in this case, i.e. Ivax, cannot forfeit its exclusivity period is not based on an assumption, but rather the texts of the Hatch-Waxman Act and the MMA. *See* discussion *supra* note 2. As discussed, the MMA amendments to the Hatch-Waxman Act include a grandfather provision that specifically exempts a certain class of Paragraph IV ANDA filers, including Ivax, from being subject to the MMA's 180-day exclusivity forfeiture provisions. Accordingly, it cannot plausibly be argued that Ivax may nevertheless forfeit its exclusivity period.

Third, the dissent states that our analysis "assumes that [Caraco] will prevail in its non-infringement claim – an uncertain assumption at best." We make no such assumption, nor need we. A plaintiff need not prove it will prevail on the merits of its case in order to prove that it has standing to bring the case. *Steel Co.*, 523 U.S. at 89 ("It is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, i.e., the courts' statutory or constitutional power to adjudicate the case.").

creates a potential for lost profits. Accordingly, Caraco's action is ripe for judicial review.

C. Mootness

The mootness doctrine requires that the requisite personal stake that is required for a party to have standing at the outset of an action must continue to exist throughout all stages of the action. *Geraghty*, 445 U.S. at 397, 100 S. Ct. 1202. The Supreme Court has articulated the mootness standard as follows:

> Simply stated, a case is moot when the issues presented are no longer "live" or the parties lack a legally cognizable interest in the outcome. Where one of the several issues presented becomes moot, the remaining live issues supply the constitutional requirement of a case or controversy.

Powell v. McCormack, 395 U.S. 486, 496-97, 89 S. Ct. 1944, 23 L. Ed. 2d 491 (1969) (internal citations omitted). The question here is whether Forest's unilateral covenant not to sue Caraco on the '941 patent renders Caraco's declaratory judgment action moot.

To be sure, Forest's covenant not to sue eliminates any reasonable apprehension of suit on the '941 patent. If a threat of suit was the only action allegedly taken by Forest that effectively excluded Caraco from the marketplace, the covenant not to sue would moot Caraco's case and divest the district court of Article III jurisdiction. *See, e.g.*, *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058-59 (Fed. Cir. 1995). *But see Fort*

James Corp. v. Solo Cup Co., 412 F.3d 1340, 1347-49 (Fed. Cir. 2005) (holding that a patentee's covenant not to sue an alleged infringer after a jury verdict of noninfringement did not moot the alleged infringer's counterclaim for unenforceability). However, Caraco does not only allege that it has a reasonable apprehension of suit on the '941 patent. Caraco also alleges that the listing of the '941 patent in the Orange Book effectively prevents Caraco from entering the drug market. Essentially, Caraco is alleging that it has been denied entry to the market in a manner that is unique to the Hatch-Waxman context.

Clearly, in the ordinary infringement context, even when a patentee maintains that its patents are valid and infringed by a potential defendant, a covenant not to sue allows the recipient to enter the marketplace. Indeed, a covenant not to sue on a patent ensures that the covenant's recipient will not be liable for damages or subject to an injunction for infringement of that patent. However, in the Hatch-Waxman context, regardless of a covenant not to sue, a generic drug manufacturer cannot enter the market without FDA approval. Moreover, an NDA holder's covenant not to sue a subsequent Paragraph IV ANDA filer does not affect the FDA's authority to approve the ANDA. As discussed above, where the first Paragraph IV ANDA filer fails to trigger its own exclusivity period, a subsequent Paragraph IV ANDA filer can only obtain FDA approval before the relevant Orange-Book-listed patents expire by obtaining a judgment that those patents are invalid or not infringed. Such a judgment is required to trigger the first Paragraph IV ANDA filer's exclusivity period and thus allow the FDA to approve the subsequent Paragraph IV ANDA 181

days after the triggering event. Under these circumstances, even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771.

Here, Forest's covenant not to sue Caraco does not allow Caraco to enter the generic drug market. Only by obtaining a judgment of noninfringement on both the '712 and '941 patents can Caraco trigger Ivax's 180-day exclusivity period, which currently prevents the FDA from approving Caraco's ANDA. Without a judgment of noninfringement on the '941 patent, even if Caraco prevailed against Forest in the separate infringement action on the '712 patent, Caraco would not be able to activate Ivax's exclusivity period via the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Moreover, until Ivax's exclusivity period expires, the FDA cannot approve Caraco's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Thus, terminating this action without a judgment with respect to infringement on the '941 patent could delay FDA approval of Caraco's ANDA and thereby exclude Caraco from the drug market, even if its generic drug does not infringe the '941 patent. In these circumstances, Forest's covenant not to sue Caraco does not eliminate the controversy between the parties.

In sum, Caraco's declaratory judgment action presents an Article III controversy as to whether the drug described in Caraco's ANDA infringes Forest's

Orange-Book-listed '941 patent. This controversy is not premised only upon a threat of an infringement suit. A controversy also exists because Forest's actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market. Forest's covenant not to sue does not eliminate the controversy with Caraco, because the controversy can only be resolved by a judgment that determines whether Forest's '941 patent is infringed by the drug described in Caraco's ANDA. Accordingly, we hold that this action presents an ongoing Article III case and controversy.

IV. CONCLUSION

For the foregoing reasons, we reverse the district court's decision dismissing Caraco's declaratory judgment action and remand for further consideration.

REVERSED AND *REMANDED*

FRIEDMAN, Senior Circuit Judge, dissenting.

I would affirm.

I

A. In most instances an alleged infringer seeks a declaratory judgment of non-infringement or patent invalidity to protect itself from a subsequent judicial determination that has a significant adverse financial impact upon the infringer. The present case involves no such danger or possibility, since the covenant not to sue precludes Forest (the proprietary manufacturer) from subjecting Caraco (the generic manufacturer) to damages for infringement of the '941 patent.

Here Caraco's reason for seeking a declaratory judgment of non-infringement is quite different. Its concern is not that it may be sued for infringement if it markets its generic version of the patented drug, but that unless it can obtain a present judicial determination of that issue, its ability to enter the market may be delayed. This claim stems from and is based upon the particular provisions of the Hatch-Waxman Act.

Under that Act someone seeking to market a generic version of a patented drug files an Abbreviated New Drug Application (known as an "ANDA"). The filing of an ANDA constitutes an act of infringement. If, within forty-five days of receiving a notice of such filing that alleges that the patent on the drug is invalid or that the proposed generic drug does not infringe the patent, the proprietary manufacturer sues the generic

manufacturer for infringement, the Food and Drug Administration cannot approve the ANDA for thirty months. The Act also provides that the first generic manufacturer to file an ANDA covering the patented drug has the exclusive right to sell such generic product for 180 days following the first sale of the generic product or a court decision holding the patent invalid or not infringed. This provision, under which the 180-day period of exclusivity is triggered by a judicial decision holding the patent invalid or not infringed, is the basis for Caraco's contention that there was an actual case or controversy before the district court despite Forest's covenant not to sue for infringement.

The theory, as I understand it and as the court apparently views it, is that the other generic manufacturers who filed first might not begin to sell their generic product upon either the expiration of the thirty month stay period or of the patents, and because the generic manufacturers cannot begin selling their products until 180 days after the first-filing generic manufacturer begins its sales, the result of such earlier filing by the generic manufacturer may be to delay Caraco's ability to begin marketing its product for a substantial period, or even indefinitely. Caraco thus contends, and the court holds, that it should be able to invoke the alternative statutory triggering mechanism for the 180-day exclusivity period—a judicial determination of patent non-infringement or invalidity—by maintaining its declaratory-judgment litigation.

This argument is highly speculative and conjectural, and involves uncertain legal issues that have not yet been resolved.

I have no basis for concluding that the first-filing generic manufacturer will, or is likely to, delay bringing its product to market after the '712 patent expires. Indeed, such delay would seem inconsistent with that manufacturer's being the first to file its ANDA—a situation it presumably sought to give it the competitive advantage of having the exclusive right to sell its generic products for the first 180-days after that product went on the market.

The argument also assumes that the 180-day exclusivity period would not begin to run until the generic manufacturer actually begins marketing its product, and any delay in such marketing will simply defer the beginning of the 180-day period. It could plausibly be argued, however, that despite the seemingly absolute nature of the statutory 180-day exclusivity, a generic manufacturer that unreasonably delays the commencement of marketing after the thirty month period and the patent term have expired, loses its right to exclusivity. Indeed, although the issue has not been raised in this appeal, it could be argued that the thirty month period itself terminates if, after triggering that period by suing the generic manufacturer for infringement after it files its ANDA, the proprietary manufacturer in effect vitiates such action by executing a covenant not to sue for infringement and dismissing its infringement suit.

Finally, Caraco's argument assumes that it will prevail in its non-infringement claim—an uncertain assumption at best.

In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 S. Ct. 764, 771, 166 L. Ed. 2d 604 (2007),

the Supreme Court recently stated that "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" Considering all the circumstances here, I answer that question negatively.

B. The court twice cites the legislative history of the Hatch-Waxman Act. The "history" that it cites, however, consists exclusively of statements during the debate on the legislation made by Senator Kennedy, whom it describes as the "ranking member" of the Senate committee.

Senator Kennedy, however, was not a sponsor of the legislation. There is no indication that his statements reflected the views of the majority of the committee or of the Senate, or the sponsors of the legislation. In my view, Senator Kennedy's statements do not provide an appropriate or adequate basis for determining the scope and meaning of this legislation. *See Garcia v. United States*, 469 U.S. 70, 76, 105 S. Ct. 479, 83 L. Ed. 2d 472 (1984) ("In surveying legislative history we have repeatedly stated that the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill, which 'represen[t] the considered and collective understanding of those Congressmen involved in drafting and studying proposed legislation.' We have eschewed reliance on the passing comments of one Member, and casual statements from the floor debates." (citations omitted)).

If, however, Senator Kennedy's comments are an appropriate source for determining the meaning of the statute, I would give considerable weight to his statement quoted in footnote 14 of the court's opinion, that: "We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe." I do not agree with the court that this statement "only emphasize[s] Congress's intent that that jurisdiction of federal courts to resolve CAPCs would extend to the limits of the Constitution."

C. The court contends that its decision is appropriate and necessary to avoid a defeat of the objectives Congress sought to achieve in the Hatch-Waxman Act that, it concludes, would result from permitting a proprietary manufacturer to use covenants not to sue to preclude generic manufacturers from obtaining declaratory judgments on patent infringement and validity. To the extent that Congress may conclude that particular judicial interpretations of the Act thwart the purposes of the legislation, it is for Congress, not for this court, to make whatever changes in the Act it deems appropriate.

II

Although I disagree with the court's substantive rulings, I agree with the court's apparent rejection of Forest's contention that Caraco's appeal was frivolous and seeking sanctions of therefor. The appeal presents important questions under the Hatch-Waxman Act that this court has not

previously decided. Under no circumstances could the appeal fairly be characterized as frivolous. Indeed, it is difficult to see how an appeal in which the appellant prevails and the appellate court adopts its contentions could be so described.

Perhaps Forest made the frivolity contention under the misguided belief that by doing so it was enhancing its prospects of success on the merits. If that was its view, it was sadly mistaken. In making the frivolity argument, which occupied five pages of its brief, Forest's counsel was neither helping his client's case nor aiding the court in performing its appellate function. In my view, a lawyer who makes such a contention of frivolity—and at the close of his oral argument, Forest's counsel stated he continued to characterize this appeal as frivolous—engages in sanctionable conduct.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 2007-1404

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Plaintiff-Appellant,

versus

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., AND H. LUNDBECK A/S.

Defendants-Appellees,

Appeal from the United States District Court for the Eastern District of Michigan in Case No. 07-CV-10737, Chief Judge Bernard A. Friedman.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellees,* and a response thereto having been invited by the court and filed by the Appellant, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

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* Amici curiae, Pfizer Inc.; Washington Legal Foundation; Merck & Co., Inc.; Pharmaceutical Research and Manufacturers of America, et al.; and Ivax Pharmaceuticals, Inc. were granted leave to file briefs in support of the Appellees combined petition for panel rehearing and for rehearing en banc.

The mandate of the court will issue on July 1, 2008.

FOR THE COURT,

/s/Jan Horbaly/JB
Jan Horbaly
Clerk

Dated: 06/24/08

cc: James F. Hurst
Gerald J. Flattmann, Jr.
All Amici

CARACO PHARMA V FOREST LABS, 2007-1404
(DCT - 07-cv-10737)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff,

Civil Action No. 07-CV-10737-DT

vs.

FOREST LABORATORIES, INC., et al.,
Defendants,

HON. BERNARD A. FRIEDMAN

_____/

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION (DKT. NO. 8)

On May 30, 2007, this matter came before the Court on Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction. A hearing was held and oral argument heard. For the reasons stated on the record,

IT IS ORDERED that Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction is granted.

IT IS FURTHER ORDERED that Plaintiff's Complaint is dismissed.

/s/Bernard A. Friedman
BERNARD A. FRIEDMAN
CHIEF UNITED STATES DISTRICT JUDGE

Dated: May 31, 2007
Detroit, Michigan

I hereby certify that a copy of the foregoing document was served upon counsel of record by electronic and/or first-class mail.

/s/Carol Mullins
Case Manager to Chief Judge Friedman

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

CARACO PHARMACEUTICAL

LABORATORIES, LTD.,

Plaintiff,

Case Number:

–v–

07–10737

FOREST LABORATORIES,

INC., et al.,

Defendants,

_____/

DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

BEFORE THE HONORABLE

BERNARD A. FRIEDMAN

UNITED STATES DISTRICT JUDGE

238 U. S. Courthouse & Federal Building

231 West Lafayette Boulevard West

Detroit, Michigan 48226

WEDNESDAY, MAY 30TH, 2007

APPEARANCES:

For the Plaintiff: Derek Sarafa, Esq.
Raymond Ruthledge [*sic*], Esq.

For the Defendants: Gerald J. Flattmann, Esq.

Court Reporter : Joan L. Morgan, CSR
Official Court Reporter

Proceedings recorded by mechanical stenography.
Transcript produced by computer-assisted transcription.

Detroit, Michigan

Wednesday, May 30th, 2007

-- --- --

THE CLERK: Calling Caraco Pharmaceutical Laboratories versus Forest Laboratories, case number 07-10737.

THE COURT: Good afternoon.

MR. SARAFA: Judge, a little housekeeping before we go to the case.

THE COURT: Housekeeping.

MR. SARAFA: My colleague, Sam Park, whom I have known, four or five years, he would be a tribute to the Bar here in the Eastern District of Michigan. I'd like to take this opportunity to move his admission.

(Attorney Admission, not on record.)

THE COURT: Appearances.

MR. FLATTMANN: Your, Honor, good afternoon.

Gerald Flattmann, from Kirkland & Ellis, for the defendants in case, Forest and Lundbeck. With me are my colleague, Christine Woogis [*sic*] (ph.), Mr. Ron King from the Clark Hill firm. Also from Forest Laboratories, Eric Bagadino [*sic*] (ph.) as patent counsel.

THE COURT: Thank you.

MR. BOLTON: Jordan Bolton from Clark Hill.

MR. SARAFA: Derek Sarafa, for Caraco Pharmaceutical. With me is my colleague, Sam Park, Ray Ruthledge [*sic*], local counsel. Also the general counsel of Caraco, Steven Walker.

THE COURT: Okay. Defendants' Motion.

MR. FLATTMANN: Thank you, your Honor.

Your Honor, this is a Motion to Dismiss for lack of subject matter jurisdiction, and we are the declaratory judgment defendant in this particular case.

Your Honor, the motion before you I would submit presents a question that's actually a pretty simple one on the facts that are raised by Caraco's declaratory judgment complaint. It's a question of whether that complaint alleges case or controversy between the parties under Article III of the Constitution. Or, it's really asking you to issue an impermissible advisory opinion.

Here, the facts are clear that Caraco is seeking an impermissible advisory opinion on a moot question. And it's doing that as a means to an end. You know, we talked about the Hatch-Waxman framework report, and one of the most important parts of that Hatch-Waxman framework is the 180 days of exclusivity that's given to the generic filer that decides to take the first risk in challenging a patent and becomes the first filer of an ANDA, an Abbreviated New Drug Application.

Caraco was not that party here. That party was Ivax Pharmaceuticals which did take that risk with regard to both the '712 patent which is before you in another case, and on the '941 patent that we're discussing today.

Now, that wasn't an Ivax exclusivity, it's Ivax's and Ivax's alone. And what Caraco is trying to do with this declaratory judgment complaint is to

trigger Ivax's 180 days. One of the ways it can trigger that is through a judgment of non-infringing. That's one of the many ways that it can be done. And they're looking to do that here in order to sort of make an end —

THE COURT: What's your — your real bottom line is covenant not to sue.

MR. FLATTMANN: That's right, your Honor.

THE COURT: And you haven't done it, and you have 13 or 14 others and you haven't done it there. The real bottom line is there's no controversy.

MR. FLATTMANN: There's no controversy here.

THE COURT: Is that your bottom line?

MR. FLATTMANN: That's my bottom line.

THE COURT: Okay.

MR. FLATTMANN: There's one count in the complaint, your Honor. It's a declaratory judgment of a non-infringement claim.

THE COURT: On the '941.

MR. FLATTMANN: Of the '941.

THE COURT: And you've had 14 or 13 other people that are doing the same thing and you haven't sued them.

MR. FLATTMANN: I haven't sued them.

THE COURT: Any indication you're going to sue these folks?

MR. FLATTMANN: Well, we can't sue them. We just gave them a covenant not to sue which forever estops us.

THE COURT: Isn't that your best shot? That's what the bottom line is —

MR. FLATTMANN: It's simple. That's all there is to it.

THE COURT: That's how I see it.

MR. FLATTMANN: And they're asking for an advisory opinion. And I could go on and tell you about the Supreme Court cases that have come down that they've tried to use to sort of leverage or bootstrap themselves into future customers here, but the fact remains there's only claim in their DJ complaint and it's gone, it's mooted.

THE COURT: Okay.

MR. FLATTMANN: Okay.

THE COURT: I want to see the chart.

MR. SARAFA: Judge, the covenant not to sue absolutely does not resolve the controversy, okay, and it's absolutely clear in Novartis and it's clear in MedImmune, the only way you could rule in their favor on the point, your Honor, is if you ignored those two decisions, period .

THE COURT: Doesn't it differentiate —

MR. SARAFA: No, it can't and I'll tell you why. It's very simple.

Here is the language from the Novartis decision. There's no question — there's no question in binding authority, your Honor. There's no question — this is just the language from the case, your Honor. There's no question —

THE COURT: Oh, you want me to read it. Okay.

MR. SARAFA: There's no question binding authority, your Honor. There's no question it is identical in every respect, they agree, with the exception of the covenant not to sue —

THE COURT: With the exception of the covenant not to sue.

MR. SARAFA: Your Honor, look at the language of the case. Now, the case considered five factors, five factors, okay? Here's what it says in three of them.

> "A justiciable declaratory judgment controversy arises for an ANDA filer when (1) a patentee lists patents in the Orange Book . . ."
>
> That's undisputed, that's the case here.

"(2) The ANDA applicant files its ANDA certifying the listed patents under paragraph IV . . ."

No dispute.

"(3) The patentee brings an action against the submitted ANDA on one or more of the patents . . ."

No dispute.

And then the case says,

"The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents."

Your Honor, that ends the inquiry.

THE COURT: Whoa, Whoa. Go back to three for a second.

MR. SARAFA: Three.

THE COURT: "The patentee brings an action against the submitted ANDA . . ."

MR. SARAFA: And there's no dispute on that.

THE COURT: ". . . on one or more of the patents."

MR. SARAFA: Yes, they agree. They've done it. They've sued on the '712. They have brought an action.

Your Honor, there's no dispute. You can ask Mr. Flattmann, right now —

THE COURT: Go on.

MR. SARAFA: There's no dispute.

Judge, dispositive. Dispositive means that's the end of the inquiry. Now, your Honor, this was not a case where the Court didn't consider the possibility of a covenant not to sue. There were two other circumstances the Court considered. One was the legislative history, and the other was the existence or non-existence of a covenant not to sue. Here's what the Court said as to that. It didn't say it was dispositive, Judge. It said, that a covenant not to sue is a fifth circumstance contributing to a finding that Teva has the justiciable declaratory judgment controversy. Contributed.

And in the same opinion it tells you that these three factors are dispositive, Judge. It can't be any clearer than that. Cannot be any clearer than that. The decision — your Honor has obviously read the decision and I encourage you to read it again, your Honor. There are no two ways about it. The decision did not hinge on the existence or non-existence of a covenant not to sue.

And what is more, your Honor, it couldn't possibly because the Supreme Court in MedImmune just rejected the exact argument that they're making here, the exact argument in the MedImmune decision that's only a few months old, Judge.

What happened in that case was the party that brought the declaratory judgment action had a fully paid up license. Now in the law and there's case law on this, a paid up license is the same as a covenant not to sue. Same thing. Same thing. Case law is clear on this point. We get a license, you're saying you don't sue me and I give you money. It's the same thing as a covenant not to sue.

The declaratory judgment defendant or the patent holder in that case could not have brought a cause of action. There was no underlying cause of action that they could have brought against the licensee. It was impossible.

In fact, the Supreme Court said quite clearly that the risk of being sued was, and I quote, "At least remote, if not, is non-existent." As long as those payments are made there is no risk that respondents will seek to enjoin petitioner. Yet, the Supreme Court went on to say, there was still a controversy in a case that is basically a covenant not to sue, the effective equivalent of a covenant not to sue. The Court recognized jurisdiction can exist, "even though the very reason the plaintiff sought declaratory relief was that the defendant had given no indication he would file suit."

So, Judge, respectfully, the covenant not to sue is not the Novartis decision which is binding on your Honor, did hinge upon it. The idea that a covenant can moot the controversy has been rejected by the MedImmune Court and, more importantly, Judge, it doesn't remove the controversy. The Novartis decision was very clear. The controversy is just not infringement or non-infringement. The controversy

is whether or not our ANDA can be approved so we can sell a generic version of our drug — a generic version of Lexapro.

And the opinion in Novartis was exceedingly clear on that point. Here's what they said. Here's what the Novartis court said — he's trying to make it out to be a situation where there's just one case and there's one count, but that argument was expressly made and rejected in Novartis. Here's what Novartis, Judge.

THE COURT: Tell me where you're reading, because I'm reading the section — I've got the case right here.

MR. SARAFA: Okay. I don't know which version your Honor as, but —

THE COURT: I have the West law —

MR. SARAFA: Okay.

THE COURT: Just tell me where it is.

MR. SARAFA: Judge, if you look under head note 2223.

THE COURT: Which version do you have?

MR. SARAFA: I have — I think it's West law.

THE COURT: What page?

MR. SARAFA: On mine, it's page 11.

THE COURT: Okay.

MR. SARAFA: On the left-hand column.

I want to be clear on this, Judge, what they're saying is, there's one count, and that count is mooted by a covenant. And what the Novartis court specifically explained it, you don't look at it like that, that's not the controversy. The controversy is both cases. The controversy is getting our ANDA approved. Here's what the Court said,

"While it is true that the suit on the 937" —

THE COURT: You're reading where? The middle of page 11?

MR. SARAFA: Middle of the way down on the left-hand column, starting with "While."

THE COURT: Okay starting with —

MR. SARAFA: "While it is true . . ."

THE COURT: Okay, give it to me.

MR. SARAFA: Here's what it says,

> "While it is true, that the suit on the '937 patent is a different 'case' than Teva's declaratory judgment action . . ." same circumstance we have here.
>
> "Novartis created a present and actual 'controversy' by choosing to sue under 35 U.S.C. 271 (e) (2) (A) on Teva's single act of infringement, thereby placing into actual dispute of the soundness of Teva's ANDA, and Teva's ability to

> secure approval of the ANDA. Thus, while Teva's declaratory judgment action and the pending 937 suit are different 'cases' they arise from the same controversy created when Novartis listed its Famvir patents in the Orange Book. Teva submitted its ANDA certifying all five Famvir patents under paragraph IV, and Novartis sued Teva challenging the submission of Teva's ANDA."

Judge, this case came out two months ago. It's indisputably binding on your Honor, and what it said is the controversy is not infringement or non-infringement. The controversy is whether or not our ANDA can be approved. And that makes sense, Judge. The whole reason we have this lawsuit is so we can get onto the market with our generic version of the product. And then provide in the covenant not to sue, it doesn't eliminate that controversy it exacerbates it, Judge, it makes it worse because they know that if they do that, we can't get an order stating that we don't infringe. Judge, they admit we don't infringe the '941 patent. They've admitted it. All we need is an order from your Honor saying it's dismissed on that basis. If they have nothing to lose here, Judge, why are they fighting tooth and nail to get this dismissed on the basis of a lack of subject matter jurisdiction.

I urge you to ask Mr. Flattmann that same question because this could be over in about 20 seconds, Judge. I move for summary judgment, they don't resist, your Honor grants the order, they don't spend any expenses. If they don't have anything at

stake, Judge, why don't we do that and — if your Honor will just indulge me for a few minutes.

I tried for a security, Judge. It's somewhere it the range of 20 billion to 70 billion dollars. They say they don't have a horse in this race. Your Honor, it's just not true. It's just absolutely untrue. If they didn't have a horse in this race, if they didn't want to spend the money being, quote, unquote, dragged into pointless litigation, what they would do is provide us what we need, an order saying we don't infringe. Why are we doing it, Judge? Let me show you: the '712 patent which they have asserted against us expired in 2005. The '941 patent they agree we don't infringe, expires in 2023. The reality is, Judge, these ten years right here, we can't go to market because of this patent that they agree we don't infringe. And for them, this equates to about 70 million dollars because if there's generic competition during that time, Judge, what that means is they will lose 80 to 90 percent of their revenues, their revenues are about 5 to 60 billion dollars a year. It's about 70 billion.

Now, Judge, if Ivax loses their case on the '712 patent, they lose that exclusivity. And what that should mean for us is if we win on the '712 patent which is the only patent they claim we infringed, we ought to be able to market. So what are they doing here? They're using this patent and by not asserting it, they are getting the benefit of a monopoly protection anywhere in the range from an additional 10 to 15 years.

Now, it's possible, it's possible that Ivax could launch after the expiration of the '712 patent, and

we would launch six months after that. But what does that mean, Judge? That means we win tomorrow on the '712 patent. We win tomorrow on the only patent they're asserting against us. We still can't go to market. We still can't go to market because of this unasserted patent.

And, Judge, this is something of their own making. They listed the patent in the Orange Book. They took the statutory protection of the Hatch-Waxman Act including the 30-month stay and everything else that goes with it —

THE COURT: Tell me why you can't go to market.

MR. SARAFA: Very simple, Judge. We can't go to market until 180 days after the expiration of Ivax's exclusivity. And what that means is if Ivax wins their suit, good for them. More power to them. They get that exclusivity —

THE COURT: For a 180 days.

MR. SARAFA: They're making it sound like we're doing something improper, we're not.

THE COURT : Okay.

MR. SARAFA: If they win, they get it.

THE COURT: Okay, what if they don't get it?

MR. SARAFA: They've already lost, okay, so — and if they lose on appeal, then the '712 is not — it doesn't impair us.

THE COURT: Right.

MR. SARAFA: Okay.

THE COURT: Why does the '941 —

MR. SARAFA: Because they have exclusivity on both. They have exclusivity on the '941 and the '712. But, Judge, why would they get the benefit of the — why would they get the benefit of the exclusivity on the '941? They can't even come to market because the '712 is locked.

THE COURT: And they get exclusivity on the '941 why?

MR. SARAFA: Because they were the first to file on that.

THE COURT: Do they get that forever or just for the 180 days?

MR. SARAFA: The 180 days. So what that means, Judge, is because of this patent, which they agree we don't infringe, we can't launch for 180 days after the expiration of that patent, we're in 2023

Judge, please —

THE COURT: Well, wait. Even today since you don't infringe if you want to do it and you have the authority to do it, you could do it.

MR. SARAFA: No, we couldn't.

THE COURT: Why not?

MR. SARAFA: We can't do it because the way — because we're barred by law. The FDA cannot approve our ANDA under those circumstances.

THE COURT: All right.

MR. SARAFA: Judge, why should they be entitled to a monopoly profit to billions of dollars —

THE COURT: That's not the issue. The issue is not —

MR. SARAFA: Okay. Why should we be harmed to the tune of tens of millions of dollars or hundreds of millions of dollars —

THE COURT: Still not the issue. Why do I have jurisdiction? It's not an equity.

MR. SARAFA: Very simple, Judge. You have jurisdiction because the fact that their listing of this in the Orange Book, and they're invoking the statutory protection and the benefits they weep from the statutory protection means that there is a controversy here. The fact that we can make of hundreds of millions and make them lose billions is better evidence of that — of the existence of that controversy. Judge, if this is not a controversy it must be the biggest non-controversy in the history of mankind.

THE COURT: You have the case — look on the page. Is your 19 pages?

MR. SARAFA: Let me see. Of course, not, it's 16 pages.

But why don't you give me a head note number, the little note.

THE COURT: It's —

MR. SARAFA: If you tell me the passage, I may know it.

THE COURT: The passage is,

> "We believe that the only circumstance in which a case of controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe."

MR. SARAFA: Yes, does not — does not remotely affect your Honor's opinion in this case.

THE COURT: Tell me why.

MR. SARAFA: For several reasons, Judge. Number one, it says "might." Not exactly a resounding — it's from legislative history and it says "might." The reason it says "might" is because it probably doesn't know about all the possible circumstances that could arise.

The second point, Judge, this was pre-MedImmune, preNovartis decision. This is based on the existence of the quote, unquote, reasonable apprehension test. When you're dealing with reasonable apprehension, that makes sense. There

can't be a reasonable apprehension if there's a covenant not to sue.

But, Judge, MedImmune changed that dramatically. It explicitly threw out reasonable apprehension, threw it out, it's gone, and took a much broader all of the circumstance approach. Why did it do that? Because it was presented to the case just like the one here. There was license which was effectively a covenant not to sue. But, Judge, there was a controversy underneath, and it broadened it and said you have to be broader than reasonable apprehension. You have to have all the circumstances.

THE COURT: If you're not violating the '941 patent, what kind of declaratory relief do you want —

MR. SARAFA: Very simple, Judge. All we need is an order saying the case is dismissed because we do not infringe the '941 patent. And since they agree that we don't, it should be pretty easy to do. I think it would take about 30 seconds, at the most —

THE COURT: What would that do for you?

MR. SARAFA: What that does, is that — this exclusivity that otherwise would exist, it triggers it. It starts running and it basically moots it out. So it doesn't prevent us from going onto the market.

Now, Judge, that exclusivity is borne out of their action.

THE COURT: In the covenant not to sue, that wouldn't give it back to you?

MR. SARAFA: Of course not. That's why they did it that way. That's exactly why they did it. That's why even though they admit —

THE COURT: But they're entitled to do it that way.

MR. SARAFA: No, no, they're not. They can do it that way, but it still leads to controversy. The controversy, Judge, is whether or not we can get to market. That's what this whole — the Hatch-Waxman Act is about. It's generic competition to the market sooner. It's to get you heads up or down on whether you're likely to infringe the patent.

And what they're doing — and, actually, Judge, they're not letting us get that. The existence of the covenant says you can't get a fair adjudication of whether or not you infringed. This whole reason they're doing it; that way, Judge, is to prevent a decision on the merits. They admit we don't infringe. They're not going to resist non-infringement. They made it very clear. So why shouldn't we get the decision on the merits?

Judge, they put this patent in the Orange Book. When they do that, they say to the world, this protects our drug. They get all the benefits that come with that.

The Novartis case is very clear. It said you cannot simultaneously leverage the benefits of the Act and shrink from your responsibilities.

THE COURT: I've got you now. You've convinced me. Let me go back to the other side. Let's see if you can re-convince me.

MR. FLATTMANN: Okay. Your Honor, Novartis and MedImmune did not change the basic constitutional rule that you need to have a case of controversy and that you can't make an advisory opinion. I'd like to —

THE COURT: But isn't there a controversy here?

MR. FLATTMANN: There's no controversy here.

THE COURT: There's no controversy because you agreed that the '941 does not infringe.

MR. FLATTMANN: No, your Honor. There is no controversy because we gave a covenant not to sue.

THE COURT: Assume you believe the '941 is infringed.

MR. FLATTMANN: Your Honor, I don't know the answer to that question.

THE COURT: That's fair.

MR. FLATTMANN: And would never admit it or said anything like what counsel said concerning infringement.

THE COURT: Let me ask you this

MR. FLATTMANN: Yes, your Honor.

THE COURT: Do you agree with his analysis that if the '941 is not infringed then the 180 days will not apply to them?

MR. FLATTMANN: I don't necessarily agree with that.

THE COURT: Tell me why.

MR. FLATTMANN: A 180 days is applicable to the '712 patent as well. Ivax had full exclusivity on those patents. What counsel explained to you was one of many possible computations that could result in a situation that he mentioned —

THE COURT: Is that one of them?

MR. FLATTMANN: That is one of —

THE COURT: Assuming the '712, the — the suit is over in a 180 days, do you believe they have to wait another 180 days on the '941?

MR. FLATTMANN: I don't know. I think that's somewhat vague part of the law. There's one decision out of the D. C. Circuit that they cite —

THE COURT: Certainly your company could take the position they don't have more competition that they have to wait a 180 days. It's a good decision for you, for your company.

MR. FLATTMANN: Well, it's a good decision I think for Ivax. Whether it's a good decision for us — it could be an irrelevant decision for us depending on whether Ivax —

THE COURT: Assuming it is on the market —

MR. FLATTMANN: One generic is on the market the prices erode and the market is essentially gone.

THE COURT: But it's still a determent [*sic*] to them if they have to wait a 180 days.

MR. FLATTMANN: It could be, your Honor. But that's an economic interest. It's not a legal interest, and it's not a case of controversy under the constitution.

What they're asking for is, is sort of an observant result. They're asking you to decide whether the '941 patent is infringed when I've already given them a covenant, my client has already given them a covenant never to sue to infringement.

THE COURT: Have you given anyone else —

MR. FLATTMANN: I'm sorry, your Honor?

THE COURT: Have you given anybody else one of them or are you prepared to do so?

MR. FLATTMANN: No, we haven't encountered any of those situations with the '941 patent.

THE COURT: Why did you put it in the Orange Book?

MR. FLATTMANN: Because we're required to do so by law and because it covers our product. Any composition of the patent it covers, it must be listed in the Orange Book.

But, your Honor, their economic interest, their economic complaint which is by the way speculative, it depends on one possible scenario, one possibility. It's what they pledged in their complaint. It's not what they're asking you to do.

Their beef is with Congress about what they perceived to be the inequities of a 180 days with specific rules and with the impact that it has on them as a second or third filer.

It's not a controversy as the Maryland Casualty case put it between two parties having adverse legal interest in this action. There's only one count as you said — as I said at the very beginning of this argument. That count is gone because of our covenant not to sue.

A consent judgment would be inappropriate at this point and would also lack jurisdiction now with the covenant not to sue is in place.

The cases that he cites to you don't stand for the proposition that he mentioned. They don't get rid of the rule that you cannot decide an abstract question, give an advisory opinion on something that's already done, namely infringement.

The Novartis case clearly noted that there was no covenant not to sue. And that case places discussion and dispositive factors which counsel mentioned to you under the Rubric Patent Uncertainty. It discussed the fact that given that patents are out there which are unasserted, and could be asserted at a later date, combined with these factors, in that context those factors are

dispositive. But in Novartis, there was no covenant not to sue.

In MedImmune there was no covenant not to sue. In that case, the Supreme Court noted right up front in the syllabus that the petitioner considers a letter from Genentech a clear threat to enforce the patent, terminate the license, and bring a patent infringement action if petitioner did not pay.

I can't do that. My client can't do that. We're forever estopped from asserting infringement of these — this patent against Caraco for — and their products. And that means there's no case of controversy before you.

So MedImmune and Novartis are entirely distinguishable. The court had it right in its opinion, the First District Court opinion to deal with Novartis, MedImmune and covenant not to sue.

And what the defendants are really looking for is a means to an end. They want to use the federal judiciary machinery as a means to an end triggering the exclusivity of the parties and the parties to the facts, your Honor.

So I submit that their beef is with Congress. Their dispute is with Congress. Maybe with the first filer, maybe with the FDA, but it's not with us, at least not as pled in this particular complaint.

And every case that has looked at, every court that has looked at a covenant not to sue in a patent infringement action and we've cited several in our brief, the Microchip case, the Amana case, the Super

Sack case, the Intellectual Property Development case, and lastly the court's decision in Merck v Apotex, which is on all fours. Every one of those found that the infringement claim as to that patent was moot, and that the court was being called upon to issue an impermissible advisory opinion which if we looked at the obserbia [*sic*] (ph) you'd be asked — I'd be asked to put on the proofs of infringement. I'd have to seek through discovery whether or not they infringed, and I'd have to prove that to you even though I'm estopped from asserting infringement against them. They, on the other hand, would be proving that they don't infringe even though I promised never to sue them for infringement. That's a classic, classic advisory opinion on an abstract question of law. And their economic interest cannot create a legal interest under the pleading here.

THE COURT: Okay. I'll give you another minute and a half or two minutes.

MR. SARAFA: Thank you, Judge, very briefly.

The Novartis decision was very clear, this is not an economic interest. Here's what it said, Judge, here's what it said.

> "Novartis' selective 937 suit" — they have a selected suit — "creates uncertainty as to Teva's legal rights under its ANDA. Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer in Teva's situation is not

> legally free to enter the market because federal statutes prohibit it. Hence, Teva suffers a direct legal injury from the actions that Novartis has already taken-Novartis' listing of the five Famvier patents int eh [*sic*] Orange Book and Novartis' suit against Teva challenging the validity of Teva's ANDA which requires judicial relief."

Judge, bottom line, he didn't deny it and he also didn't answer my question —

THE COURT: What do you think of Judge Sleet's (ph) opinion?

MR. SARAFA: I don't think it's worth the paper it's written on —

THE COURT: Oh, oh —

MR. SARAFA: Sorry, Judge —

THE COURT: Good thing I don't know him.

MR. SARAFA: Judge, with all due respect to Judge Sleet —

THE COURT: I'm teasing you.

MR. SARAFA: He doesn't cite — he doesn't cite this is a Dispositive test.

And I didn't hear Mr. Flattmann contest that the word "Dispositive" is right here, or that it is actually dispositive. The reality is, Judge, there's a bottom line here. The bottom line is we cannot get onto the

market until we get this order. The bottom line is what they've done is tantamount to an agreement that we don't infringe, and we can't even get to market without that order.

What I didn't hear him explain is why they won't just give us that order, Judge. And it's because they have so much at stake. It proves there's a controversy. I started off my argument saying give us the order saying we don't infringe if you don't have a horse in this race. He didn't even respond to that point, and it was the first thing that I mentioned. We are blocked from the market unless we receive this court order. There's only one place we can get it. It's from your Honor, and there is no reason in the world why we should be kept off the market by a patent which they agree we don't infringe. And they say, well, we didn't agree. It's tantamount to an agreement, Judge. This is a company that if there was the slightest possibility that that patent could cover us, they would have sued us in a heart beat. They agree, and they have no defense to it.

The reality is, this is not something that Ivax or the FDA caused. As stated in the Novartis opinion, when you put a patent in the Orange Book, when you take the statutory protections, when you invoke those protections and you rely on them to keep your monopoly you have certain responsibilities. You can't leverage the benefits of the act and then ignore your responsibilities. They have to allow us to get a decision up or down on the merits of the patent. That is what is required to resolve this controversy, your Honor.

Thank you.

THE COURT: Thank you.

MR. FLATTMANN: I think he made a correct statement, we did not commit infringement and that's why the covenant not to sue.

THE COURT: Okay. In this matter —two great attorneys arguing. You had me going back and forth, and we've gone over this many times, Jeff and I, on the bench memo. I've read your cases.

The Court understands Caraco's motion — argument and it's very persuasive in terms of the economics and the business in terms of the statutory scheme. However, the Court can't — I agree with the defense, I think you have to look at Congress for that. I expected to see if there's a controversy. The Court doesn't believe that there's a controversy. I went back which I had not done before and looked at the complaint on page 19, and the complaint really is asking for the same relief as they already have. There's no controversy and that means that they have a covenant not to compete so that in effect I think I couldn't give anything advisory since they're not going to sue, there's no chance.

I'm not here just — this is, in effect, a DEC action as oppose to some kind of equitable action on whether or not the statute is fair and the 180 day rule and so forth, but there's no controversy. There's a covenant not to sue on the '941 so there's not going to be any loss, there's no threat of a lawsuit. There are others that are doing the same thing. There's no lawsuits. There could be, but it doesn't appear to be.

The defendants in this particular matter have made it clear that they intend to honor the covenant not to sue. It may be a technical way of getting around having their patent examined in this setting. I don't know about all settings, but I think they're entitled to that. It's part of the practice of law and the way that we handle things, but there's got to be controversy under Article III and there's no controversy and the Court should not be involved in it. Therefore, the Court will grant the motion.

Okay. Thank you.

(Proceedings concluded.)

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CERTIFICATE

I, JOAN L. MORGAN, Official Court Reporter for the United States District Court for the Eastern District of Michigan, appointed pursuant to the provisions of Title 28, United States Code, Section 753, do hereby certify that the foregoing proceedings were had in the within entitled l and number cause of the date hereinbefore set forth, and I do hereby certify that the foregoing transcript has been I prepared by me or under my direction.

_____

JOAN L. MORGAN,
CSR

Official Court Reporter

Detroit, Michigan
48226

Date:_____

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL LABORATORIES, LTD.,

Plaintiff,

vs.

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD. and H. LUNDBECK A/S,

Defendants,

_____/

Case: 4:07-cv-10737
Assigned To: Gadola, Paul V
Referral Judge: Scheer, Donald A.
Filed: 02-20-2007 At 03:21 PM

COMPLAINT

Plaintiff Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), by its attorneys, for its Complaint against Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, "Defendants") alleges as follows:

INTRODUCTION

1. Caraco brings, and is entitled by statute to maintain, this action for declaratory judgment of patent non-infringement under, *inter alia*, the federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S. C. § 355 (j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as

amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

2. This action arises out of, *inter alia*, Caraco's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Defendants' brand-name anti-depression medication LEXAPRO®, known generically as escitalopram oxalate.

3. Defendants purport to own U.S. Patent Nos. Rc. 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent"). Upon submission by Defendants, the '712 and '941 patents were listed in FDA's compilation of approved drugs and their respective patents entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book." As a consequence of such Orange Book listing, Defendants maintain, and have affirmatively represented to the world, that the '712 and '941 patents claim the approved drug LEXAPRO®, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Caraco, attempting to market a generic escitalopram product before expiration of the '712 and '941 patents.

4. Caraco seeks to market a generic escitalopram product before the expiration of the '712 and '941 patents. Therefore, as required by the FFDCA, Caraco has certified to FDA that its ANDA products will not infringe any valid or enforceable claims of the '712 and '941 patents and has further notified

Defendants of the legal and factual bases for those certifications. Caraco's submission of the so-called paragraph IV certifications to the '712 and '941 patents constitutes an artificial act of patent infringement putting Caraco at considerable risk of being sued by Defendants both before and after market entry.

5. This regulatory submission creates the necessary case or controversy and subject matter jurisdiction for Defendants to sue Caraco – and for Caraco to obtain declaratory judgment against Defendants – regarding infringement of the '712 and '941 patents.

6. In a separate lawsuit, *Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S. v. Caraco Pharmaceutical Laboratories, Ltd.*, Case No. 2:06-cv-13143 (BAF) (MKM), Defendants, in fact, sued Caraco for infringement of the '712 patent. Defendants, to date, have not sued Caraco for infringement of the '941 patent.

7. Caraco has satisfied all substantive requirements for approval of its ANDA, and is prepared to begin commercial marketing of its competing generic product prior to expiration of the '712 and '941 patents. But Caraco's approval has been delayed and Caraco is presently prevented from competing in the escitalopram market by purported generic marketing exclusivities arising out of the '712 and '941 patents. In *Forest Laboratories, Inc., et al. v. Caraco Pharmaceutical Laboratories, Ltd.*, Case No. 2:06-cv-13143, Caraco is currently litigating and will obtain a court judgment as to the

validity, enforceability and/or infringement of the '712 patent. A declaratory judgment from this Court as to the '941 patent can alleviate Caraco's harm and allow Caraco to obtain approval of its product and compete in the lucrative escitalopram market.

8. In addition to a court order finding the '712 patent invalid and/or not infringed, unless Caraco obtains a similar court order on the '941 patent, Caraco faces potentially enormous infringement liability if it markets its generic product prior to expiration of the '941 parent. Only a declaratory judgment from this Court can alleviate this harm and allow Caraco to obtain approval of its product and compete in the escitalopram market free from such potential liability.

9. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Caraco and Defendants regarding the '941 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties. Caraco is entitled by law to bring and maintain this action for declaratory judgment of potent non-infringement under the Declaratory Judgment Act and the MMA where, as here, Defendants did not sue Caraco within 45 days of receipt of Caraco's notice of paragraph 1V certification to the '941 patent, and Caraco has offered Defendants an Offer of Confidential Access to Caraco's ANDA for generic escitalopram product.

10. Caraco is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Caraco's proposed generic escitalopram product does not and will not infringe

the '941 patent. Absent the exercise of jurisdiction by this Court and such declaratory relief, Caraco and the American public will be irreparably harmed by the substantial delay in the market entry and availability of lower-priced generic escitalopram.

THE PARTIES

11. Plaintiff Caraco Pharmaceutical Laboratories, Ltd. is a Michigan corporation having a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202.

12. Defendant Forest Laboratories. Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

13. Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation having offices at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda.

14. Defendant H. Lundbeck A/S is a Danish corporation having a principal place of business at Ottiliavej 9, DK-2500 Valby, Copenhagen, Denmark.

U.S. PATENT NO. 6,916,941

15. Upon information and belief, on July 12, 2005, the '941 patent, titled "Crystalline composition containing escitalopram" – a copy of which is attached hereto as Exhibit A – was issued to H. Lundbeck A/S as assignee.

16. Upon information and belief, the '941 patent is scheduled to expire on January 25, 2023.

17. Upon information and belief, H. Lundbeck A/S is the owner of the '941 patent.

18. Upon information and belief, Forest Laboratories Holdings, Ltd. is the exclusive licensee of the '941 patent and Forest Laboratories, Inc. holds New Drug Application ("NDA") No. 21323 on LEXAPRO® brand escitalopram oxalate tablet products.

19. Upon information and belief, Forest Laboratories Holdings, Ltd. has appointed Forest Laboratories, Inc. its exclusive distributor of LEXAPRO® brand escitalopram oxalate products in the United States.

20. Upon information and belief, Defendants have the right to sue for any infringement of the '941 patent.

JURISDICTION AND VENUE

21. Substantial, present, genuine and justiciable controversies exist between Defendants and Caraco regarding the '941 patent.

22. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271 (e)(5)).

23. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because it involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*; under the Declaratory Judgment

Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the '941 patent; and under the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. §§ 271(e)(5)), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

24. This Court can and should declare the rights and legal relations of the parties regarding the '941 patent pursuant to, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

25. Caraco has the statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over Caraco's claims pursuant to 35 U.S.C. § 271 (e)(5).

26. Upon information and belief, this Court has personal jurisdiction over Defendants because Defendants conduct substantial business in, and have regular and systematic contact with, this District.

27. Upon information and belief, Defendants maintain such a continuous and systematic contact with the State of Michigan and this District by conducting substantial, regular and systematic business therein through the marketing and sales of their pharmaceutical products, including LEXAPRO® – the purported commercial embodiment of the '941 patent – to allow this Court to reasonably exercise personal jurisdiction over Defendants.

28. This Court also has personal jurisdiction over Defendants because Defendants have submitted to the jurisdiction of this Court in a prior related litigation, *Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd,, and H. Lundbeck A/S. v. Caraco Pharmaceutical Laboratories, Ltd.*, Case No. 2:06-cv-13143 (BAF) (MKM), which is currently pending in this Court.

29. Upon information and belief, Defendants purposefully avail themselves of the privilege of doing business in the State of Michigan and in this District.

30. Venue is proper in this District under 28 U.S.C. § 1400(b). Venue is also proper in this District under 28 U.S.C. § 1391 because, *inter alia*, Defendants are subject to personal jurisdiction in this District and because Defendants are alien corporations.

BACKGROUND

I. Regulatory Framework

A. FDA Approval Of New Drug Applications (NDAs).

31. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments and Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to

approve the marketing of both brand-name and generic drugs.

32. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare an NDA for consideration by FDA. *See* 21 U.S.C. § 355.

33. The NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

34. Upon approval of the NDA, FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

35. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and, in particular, against any company that is seeking to make a generic bioequivalent of the NDA drug before patent expiration.

36. Thus, the NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can

and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

37. Such conduct by the NDA-holder/patent owner gives rise to a real and concrete belief on the generic applicant's part that it will face an infringement suit, or the threat of one, if it attempts to seek approval for or to market a generic version of the NDA drug before patent expiration.

B. Generic Competition - Abbreviated New Drug Applications (ANDA).

38. Generic drugs are versions of brand-name prescriptive drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

39. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 27l(e)).

40. Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition and to expedite the marketing of lower-priced generic drug products. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

41. To receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

42. An ANDA also must contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the listed reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

43. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12).

44. The submission of a paragraph 1V certification has two important consequences.

45. First, a generic applicant that is first to submit an ANDA containing a paragraph IV certification for a listed patent is entitled to 180 days of generic market exclusivity during which no other competing generic drug products may be marketed. 21 U.S.C. § 355(j)(5)(B)(iv). This statutory benefit to the first filer is commonly known as "180-day exclusivity."

46. In particular, the statutory provision of the FFDCA applicable here provides that "[i]f the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this section [containing] such a

certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of: (a) the first commercial marketing of that ANDA applicant's proposed drug; or, (b) a court decision – whether it involves the first applicant or not – that the particular patent that is the subject of the paragraph IV certification is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv). Thus, unless a subsequent generic applicant can obtain a court decision of noninfringement and/or invalidity as Congress intended, the approval of its ANDA can be delayed indefinitely by the purported exclusivity of the first filer.

47. Second, the submission of a paragraph IV certification for a listed patent constitutes an artificial act of infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

48. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued on the listed patent within the applicable 45-day period.

49. An applicant submitting an ANDA containing a paragraph IV certification must notify both the NDA holder and patent owner of its

paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

50. Upon receiving notice of the paragraph IV certification, the NDA holder/patent owner has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(c)(2)(A).

51. The NDA holder/patent owner's filing of a lawsuit prior to the expiration of 45 days prevents FDA from issuing final approval of the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

C. ANDA-Filer May Bring A Declaratory Judgment Action

52. On December 8, 2003, the MMA was signed into law. Title XI of the MMA, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA and, in particular, the Hatch-Waxman Amendments.

53. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/patent owner brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

54. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

55. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to Application is accepted.

56. The new declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes this proceeding.

57. Congress's intent in amending 21 U.S.C. § 355 and 35 U.S.C. § 271(e) was to extend to ANDA applicants, like Caraco here, the right to file and maintain a declaratory judgment action for patent noninfringement and/or invalidity against an NDA holder/patent owner, and to direct the district court to exercise subject matter jurisdiction in such an action.

58. The purpose of this provision was two-fold, First, Congress enacted the declaratory judgment provision to allow generic applicants to obtain court decisions that would expedite the introduction of

generic drugs by allowing the generic applicant to obtain approval of its ANDA and clear up any bottleneck in the market created by another applicant's 180-day exclusivity.

59. The FFDCA provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the listed patent invalid, unenforceable or not infringed, whichever is first.

60. These events – first commercial marketing and a court decision – are, often called triggering events, because under the statute they can trigger the beginning of he 180-day exclusivity period.

61. The 180-day exclusivity can begin to run, with a court decision by any applicant, even before the first applicant has received approval for its ANDA or before the first applicant has begun commercial marketing of the ANDA product. In that case, some, or all, of the 180-day exclusivity period could expire without the first ANDA applicant marketing its generic drug.

62. Conversely, if there is no court decision on a listed patent and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period.

63. Until an eligible ANDA applicant's 180-day exclusivity period has been triggered (and expires), FDA cannot approve subsequently submitted ANDAs for the same drug, even if the later ANDAs are otherwise ready for approval and the applicants are willing to immediately begin marketing.

64. By specifically allowing declaratory actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely by the first filer's 180-day exclusivity period. A declaratory action by a subsequent ANDA filer can result in a court decision that would trigger the first filer's 180-day exclusivity period, thereby clearing the way for approval of the subsequent ANDA filer.

65. Second, Congress intended to allow generic applicants to obtain patent certainty before marketing their generic products in order to avoid potentially catastrophic infringement damages.

66. Accordingly, if the NDA holder/patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA holder/patent owner to obtain patent certainty. Indeed, Congress explicitly mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

67. Similarly, if the NDA holder/patent owner files a lawsuit, but fails to assert a patent that was the subject to a Orange Book listing and paragraph 1V certification, the ANDA-filer is entitled to file and maintain a declaratory action against the NDA

holder/patent owner to obtain patent certainty on the non-asserted patent.

II. Caraco's ANDA No. 78-219

A. Caraco Has The Right To Bring Declaratory Lawsuit On The '941 Patent

68. In March 2006, Caraco filed an ANDA (No. 78-219) with FDA seeking generic approval for 5, 10, and 20 mg tablets of escitalopram oxalate (the "ANDA Products").

69. Defendants listed the '712 patent and the '941 patent in the Orange Book in connection with NDA No. 21323 and the brand name drug LEXAPRO®, which comprises the active ingredient escitalopram oxalate.

70. By listing the '712 and '941 patents in the Orange Rook, Defendants maintain, and have affirmatively represented to the world, that the '712 and '941 patents claim LEXAPRO®, or a method of using that drug, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Caraco, that attempts to seek approval for, and market, a generic version of LEXAPRO® before the expiration of the '712 and '941 patents. The listing of the '712 and '941 patents in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer who makes a paragraph IV certification as to the '712 and '941 patents.

71. Because Caraco seeks FDA approval to market its ANDA Products before expiration of the '712 and '941 patents, Caraco's ANDA includes paragraph IV certifications to both the '712 and '941 patents.

72. On May 24, 2006, Caraco sent to Defendants a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the '712 and '941 patents are invalid, unenforceable, and/or not infringed by Caraco's ANDA Products.

73. Upon information and belief, Defendants received Caraco's notice letter of its paragraph IV certifications on May 24, 2006.

74. On July 10, 2006, Defendants filed a patent infringement lawsuit against Caraco, alleging that Caraco's ANDA Products would infringe the '712 patent. That lawsuit is currently pending in this Court.

75. Although a case or controversy exists between the parties on the '941 patent, Defendants did not bring a lawsuit that Caraco's ANDA Products would infringe the '941 patent.

76. Caraco, on its notice letter and as required under 21 U.S.C. § 355(i)(5)(C), extended to Defendants an Offer of' Confidential Access to Application to access certain information in Caraco's ANDA for escitalopram product.

77. By providing this Offer of Confidential Access to Application, and because Defendants did

not sue Caraco on the '941 patent within 45 days of receipt of Caraco's notice of paragraph IV certification, Caraco is statutorily entitled to file and maintain a declaratory judgment action against Defendants under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

B. Caraco's Need To Obtain Court Judgment On The '941 Patent

78. Caraco is not only entitled to bring this lawsuit but requires the decision of this lawsuit to avoid indefinite delays in its approval of ANDA No 78-219.

79. Upon information and belief, Caraco is not the first ANDA filer on either the '712 patent or the '941 patent.

80. Upon information and belief, Ivax Corporation is the first ANDA filer with respect to each of the '712 and '941 patents, and, thus, arguably is entitled to a separate 180-day period of exclusivity on each of the '712 and '941 patents.

81. If this is proven true, generic competition for escitalopram products may be delayed until 180 days after expiration of the '941 patent in 2023, unless Ivax begins commercial marketing of its generic escitalopram product prior to the '941 patent's expiration date. Defendants refusal to litigate the validity and/or noninfringement of the '941 patent is purposefully preventing a court decision of invalidity, unenforceability and/or noninfringement on the '941 patent, which would trigger Ivax's 180-day exclusivity period for the '941 patent, thereby

allowing generic competition to the benefit of both Caraco and the American public.

82. Moreover, until and unless Caraco obtains a court decision of noninfringement and/or invalidity on the '941 patent, it faces potentially enormous infringement liability if it commences marketing before the '941 patent expires. Caraco can alleviate this harm and obtain patent certainty only through a declaratory judgment from this Court on the '941 patent.

COUNT I

Declaration of Noninfringement of the '941 Patent

83. Caraco realleges and incorporates by reference the allegations of Paragraphs 1-82.

84. This Declaratory Action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C), and seeks a declaration that one or more claims of the '941 patent will not be infringed by the manufacture, use, or sale of Caraco's ANDA Products.

85. A present, genuine, and justiciable controversy exists between Defendants and Caraco regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Caraco's ANDA Products would infringe one or more claims of the '941 patent.

86. The manufacture, use, or sale of Caraco's ANDA Products would not infringe the claims of the '941 patent.

87. Caraco is entitled to a declaration that the manufacture, use, or sale of its ANDA Products would not infringe the claims of the '941 patent.

Prayer for Relief

WHEREFORE, Defendant Caraco Pharmaceutical Laboratories, Ltd. respectfully requests that this Court enter a Judgment and Order in its favor and against Defendants as follows:

(a) declaring that Caraco has not infringed and that Caraco's manufacture, use, or sale of products covered by ANDA No. 78-219 would not infringe the claims of U.S. Patent No. 6,916,941;

(b) declaring that this is an exceptional case under 35 U.S.C. §§ 285 and awarding Caraco its attorneys' fees, costs, and expenses in this action; and

(c) awarding Caraco any further and additional relief as the Court deems just and proper.

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Plaintiff,

Civil Action No. 07-CV-10737-DT

vs.

FOREST LABORATORIES, INC., et al.,
Defendants,

_____/

COVENANT NOT TO SUE CARACO PHARMACEUTICAL LABORATORIES UNDER U.S. PATENT NO. 6,916,941

WHEREAS, on or about March 23, 2006, Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") filed Abbreviated New Drug Application ("ANDA") No. 78-219 seeking FDA approval to engage in the commercial manufacture, use and sale of generic versions of the branded drug LEXAPRO® (escitalopram oxalate)("the generic products");

WHEREAS, on or about May 24, 2006, Caraco sent a "Notification Pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 35(j)(2)(B)(ii) and 21 C.F.R. § 314.95" to Forest Laboratories, Inc. ("Forest") and H. Lundbeck A/S ("Lundbeck") alleging non-infringement, invalidity and/or unenforceability of U.S. Patent RE 34,712

("the '712 patent") and U.S. Patent No. 6,916,941 ("the '941 patent");

WHEREAS, on July 10, 2006, Forest and Lundbeck brought suit in the United States District Court for the Eastern District of Michigan (Case No. 2:06-cv-13143) for infringement of the '712 Patent Infringement Action"), which suit is currently pending, and wherein no claims were made based on the '941 patent;

WHEREAS, on February 20, 2007, Caraco brought suit against Forest and Lundbeck in the United States District Court for the Eastern District of Michigan, Southern Division (Case No. 4:07-cv-10737), for a declaration of non-infringement of the '941 patent ("the '941 Patent Declaratory Judgment Action"), which suit is currently pending;

WHEREAS, Forest and Lundbeck have moved to dismiss the '941 Patent Declaratory Judgment Action for lack of case or controversy;

NOW, THEREFORE, to confirm the absence of any case or controversy in the '941 Patent Declaratory Judgment Action between Forest and Lundbeck, as defendants, and Caraco, as plaintiff, regarding any infringement of the '941 patent by the generic products described by ANDA 78-219;

Forest (including Forest Holdings Ltd.) hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use, sale,

offer for sale or importation of the generic products described by ANDA 78-219; and

Lundbeck hereby covenants itself and all successors in interest to the '941 patent not to sue Caraco for any alleged infringement (whether direct or indirect) or violation of the '941 patent based on Caraco's filing of ANDA 78-219 or any commercial manufacture, use, sale, offer for sale or importation of the generic described by ANDA 78-219.

THIS COVENANT shall have no impact on Forest's and/or Lundbeck's ability to assert claims against Caraco under any patents other than the '941 patent, including, without limitation, the '712 patent, nor shall it have any impact on the pending '712 Patent Infringement Action.

FOREST LABORATORIES, INC.

_____

Charles S. Ryan
Vice President, Chief Intellectual Property Counsel
Date:

H. LUNDBECK A/S

/s/John Meidahl Peterson
John Meidahl Petersen
Divisional Director of Corporate Patents and Trademarks
Date: 13 April 2007

FOREST LABORATORIES, INC.

/s/Charles S. Ryan
Charles S. Ryan
Vice President, Chief Intellectual Property Counsel
Date: April 13, 2007

H. LUNDBECK A/S

_____
John Meidahl Petersen
Divisional Director of Corporate Patents and Trademarks
Date:

PERTINENT STATUTORY AND REGULATORY PROVISIONS

The Hatch-Waxman Act provides in pertinent part:

> Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section . . . . The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug . . . . Upon approval of the application, the Secretary shall publish [such] information . . . .

21 U.S.C. § 355(b)(1).

> An abbreviated application for a new drug shall contain . . . a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug . . . or which claims a use for such listed drug for which the applicant is seeking approval . . . —
>
> (I) that such patent information has not

been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii).

If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2000).

> It shall be an act of infringement to submit . . . an application under [21 U.S.C. § 355(j)] of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2).

> Where a person has filed an application described in paragraph (2) that includes a certification under subsection . . . (j)(2)(A)(vii)(IV) of [21 U.S.C. 355], and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by

> such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

35 U.S.C. § 271(e)(5).

Food and Drug Administration regulations issued to implement the Hatch-Waxman Act provide in pertinent part:

> (c) *Reporting requirements*— . . . .
>
> (2) *Drug substance (active ingredient), drug product (formulation or composition), and method-of-use patents*—(i) *Original Declaration.* For each patent that claims a drug substance (active ingredient), drug product (formulation and composition), or method of use, the applicant shall submit FDA Form 3542a. The following information and verification is required:
> . . . .
>
> (Q) A signed verification which states: "The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation.

I verify under penalty of perjury that the foregoing is true and correct." . . . .

21 C.F.R. § 314.53(c)(2)(i)(Q) (italics in original).